

**LOCAL DIAGNOSTIC REFERENCE LEVELS (DRLs) FOR PAEDIATRIC
CONTRASTED ABDOMINAL COMPUTED TOMOGRAPHY (CT) EXAMINATIONS
FOR NEPHROBLASTOMA**

by

Tebello Pitso

A dissertation submitted in fulfilment of the requirements
for the degree
Master of Radiography (Diagnostic)

Department of Clinical Sciences
Faculty of Health and Environmental Sciences
Central University of Technology, Free State

BLOEMFONTEIN

10 September 2024

Supervisor: Dr I-K Sebelego

Co-supervisor: Dr H Muller

DECLARATION

I, Tebello Pitso, hereby declare that *Local diagnostic reference levels (DRLs) for paediatric contrast-enhanced abdominal computed tomography (CT) examinations for nephroblastoma* is my own work and that it has not been submitted before by me or any other person to any university for the obtainment of a qualification, and that all the sources I have indicated are acknowledged as references.

24/08/2024

ACKNOWLEDGEMENTS

First, I wish to thank God for helping me to not give up on the study, and to thank God who gave me strength and hope to keep pursuing my passion.

I also want to thank my whole family for being present and supportive throughout the journey.

Dr Sebelego and Dr Muller, thank you for being patient with me. This research study would not have been possible without your willing assistance. It was a blessing to have both of you as my supervisors.

I would also like to acknowledge the Central University of Technology, Free State, for its financial support and assistance to complete this study.

I would like to thank the following people who contributed to the success of my dissertation:

- The participating hospital, the head of the department (HOD) from the participating imaging department and the radiographers. Thank you for giving me access to the department's patient records and trusting me with the login details to access the picture archiving and communication system (PACS).
- Ms Maryn Viljoen, who assisted with the statistical aspects of the study.
- Mrs Carol Keep, for the language editing of my dissertation and Mrs Theanette Mulder for verifying the references.

SUMMARY

Computed tomography (CT) has become essential to paediatric radiology with the ongoing technological developments, and has been established as an important part of the diagnostic procedure (Hojreh, Weber & Homolka, 2015:1574). However, paediatric CT poses a particular concern, since paediatric patients have a high risk from radiation (Järvinen, Seuri, Kortensniemi, Lanjunen, Hallinen, Savikurki-Heikkilä, Laarne, Perhomaa & Tyrväinen, 2015:86). Therefore, it is important to pay attention to the justification and optimisation of paediatric CT examinations (Järvinen et al., 2015:87). An essential part of optimisation is developing diagnostic reference level (DRL) values (Saravanakumar, Vaideki, Govindarajan, Devenand, Jayakumar & Sharma, 2016:342). The International Commission on Radiological Protection (ICRP) describes DRL values as a form of investigation levels applied to an easily measured quantity (Saravanakumar et al., 2016:342). Furthermore, the ICRP (2017:31) indicated that DRL values are not dose limits and are not based on individual patients but rather on a specific group of patients.

According to hospital reports, paediatric patients who presented for abdominal CT examinations at the participating hospitals were most likely to have nephroblastoma (Lesetja, 2021). It was found through a literature evaluation that no documented paediatric local DRL (LDRL) values existed for CT examinations to investigate and stage nephroblastoma in South Africa. The absence of established clinical indication-based paediatric LDRL values in South Africa limits the ability to identify unusually high dose levels, and ensure optimal radiation protection during contrast-enhanced abdominal CT examination of paediatric patients who present with nephroblastoma.

The aim of the study was to establish paediatric LDRL values for contrast-enhanced abdominal CT examinations to diagnose and stage nephroblastoma cases. To achieve the aim of this study, three objectives were pursued: (1) to develop paediatric LDRL values that are linked to the patient's weight and age for contrast-enhanced abdominal CT examination for nephroblastoma cases; (2) to compare LDRL values calculated, using weight versus effective diameter of the patient, and (3) to compare the clinical indication-based LDRL values with other internationally published clinical indication-based LDRL values.

The study followed a descriptive research design, and data from paediatric patients who underwent CT abdominal examination to diagnose nephroblastoma from 1 January 2018 to 31 December 2021 were collected retrospectively. In this research study, the researcher used a structured data recording document to descriptively gather dose information from the dose reports on the picture archiving and communication system (PACS) or CT console and the CT register file. Thereby, paediatric LDRL values for contrast-enhanced abdominal CT examinations based on the clinical referral of suspected or confirmed nephroblastoma were established. A structured data recording document was used to obtain the volume computed tomography dose index ($CTDI_{vol}$), dose length product (DLP), clinical indication, anterior-posterior (AP) dimensions, lateral (LAT) dimensions, effective diameter, age, and weight of the patients. The size-specific dose estimates (SSDE) parameters were calculated using methods provided by the American Association of Physicists in Medicine (AAPM) Report 204. The target population of this study consisted of paediatric patients who presented with nephroblastoma for contrast-enhanced abdominal CT examinations at the participating hospital. The sample size of paediatric patients who formed part of this research study was 120 patients for contrast-enhanced abdominal CT examination. The patients were categorised into five age groups (group 1 [<1 month (M)]; group 2 [1M to <4 years (Y)]; group 3 [4Y to <10 Y]; group 4 [10Y to <14 Y], and group 5 [14Y to <18 Y]) and five weight categories (group 1 [0kg - <5 kg), group 2 [5kg - <15 kg), group 3 [15kg - <30 kg), group 4 [30kg - <50 kg) and group 5 [50 kg to <80 kg)), as suggested by the ICRP (2017:93). Furthermore, the sample was also grouped according to five effective diameter groups (group 1 [<13 cm); group 2 [13 cm to <16 cm); group 3 [16 cm to <20 cm); group 4 [20 cm to <24 cm), and group 5 [<24 cm)). The effective diameter was calculated from the square root of the product of the patient's AP and LAT dimensions' measurements as suggested by ICRP (2017:97). A minimum of 20 patients for each group was needed to develop LDRL values for this study based on the 75th percentile. The data from the age, weight or effective diameter groups with fewer than 20 patients to establish LDRL values for nephroblastoma were excluded. Therefore, LDRL values were established only for

- two weight groups: weight group 2 [5kg - <15 kg), weight group 3 [15kg - <30 kg),

- three age groups: age group 2 [1M to <4Y), age group 3 [4Y to <10Y) and age group 4 [10y to <14y), and
- two effective diameter groups: effective diameter group 2 [13 cm to <16 cm) and effective diameter group 3 [16 cm to <20 cm).

The paediatric LDRL values (75th percentile) based on the CTDI_{vol} ranged from 2.7–7.1 mGy, 2.7–3.5 mGy, and 2.8–6.5 mGy for age groups, weight groups and effective diameter groups, respectively. The DLP, 75th percentile paediatric LDRL values for age groups ranged from 98.7–367.9 mGy.cm, 95.7–162.6 mGy.cm for weight groups, and 111.8–325.9 mGy.cm for effective diameter groups. The LDRL values (75th percentile) based on the SSDE parameters (AP, LAT, SUM and effective diameter) ranged from 5.6–12.8 mGy, 5.6–6.9 mGy and 5.9–12.2 mGy for age groups, weight groups and effective diameter groups, respectively. Based on a 95% confidence limit calculated on the 75th percentile, a significant difference was detected between CTDI_{vol} and SSDE parameters, indicating that both dose quantities had different effects on radiation exposure. Since the CTDI_{vol} provides only information about the scanner's output, it cannot estimate size-specific patient doses (AAPM, 2011:2). Therefore, according to AAPM (2011:18), the SSDE should be used as it incorporates corrections for patient sizes. The DLP, CTDI_{vol}, and SSDE parameters did not correlate with weight in weight group 2 (5 kg to <15 kg). The DLP, CTDI_{vol}, and SSDE parameters significantly correlated with weight group 3 (15 kg to <30 kg). The ICRP (2017:93) and European Commission (2018:32) stated that patient weight is the most reliable factor associated with the DRL quantity. Therefore, weight should still be used for categorising, as the ICRP (2017) suggested. The LDRL values calculated using weight were compared with the effective diameter of the patient. The weight and effective diameter LDRL values were comparable, and Spearman's coefficient correlation indicated a significant correlation between patient weight and effective diameter. Therefore, the weight (kg) or the effective diameter (cm) can be used to categorise the patients. However, the ICRP (2017:97) recommended that the effective diameter should be considered in addition to weight during the development of DRL values. Unlike weight and age, effective diameter represents dimensional measurement at a specific cross-sectional image, while weight and age represent the area being scanned (Cook, Chadalavada & Boom, 2013:2). This study's clinical indication-based

LDRL values were also compared with the internationally published LDRL values. No studies could be found in South Africa or internationally that have developed LDRL values, specifically for nephroblastoma in paediatric patients. The LDRL values for paediatrics developed in this study were somewhat lower than most DRL values found in various studies, except those by Hwang, Choi, Yoon, Ryu, Shin, Kim, Lee, You and Park (2021) and Almén, Guðjónsdóttir, Heimland, Højgaard, Waltenburg and Widmark (2022). The radiation dose accumulated by paediatric patients involved in this study was lower due to the number of scan sequences and the use of automatic tube current modulation (ATCM) and iterative reconstruction (IR) algorithms.

The established LDRL values in this study will contribute as a guide to optimise the radiation dose received by paediatric patients for nephroblastoma. The findings of this study further support the idea that the effective diameter groups, together with the SSDE dose quantity, should be used to develop paediatric DRL values, as suggested by ICRP (2017) and AAPM (2011).

Key terms: Computed tomography, local diagnostic reference level values, nephroblastoma, age, weight, effective diameter, size-specific dose estimates

TABLE OF CONTENTS

GLOSSARY OF TERMS	iv
LIST OF ACRONYMS AND ABBREVIATIONS	vii
LIST OF TABLES	x
LIST OF FIGURES	xii
LIST OF EQUATIONS	xiii
CHAPTER 1: INTRODUCTION AND BACKGROUND	1
1.1 INTRODUCTION	1
1.2 BACKGROUND TO THE STUDY	3
1.3 PROBLEM STATEMENT AND RESEARCH QUESTIONS	4
1.3.1 Problem statement	4
1.3.2 Research question	4
1.4 AIM AND OBJECTIVES OF THE STUDY	4
1.4.1 AIM OF THE STUDY	4
1.4.2 OBJECTIVES OF THE STUDY	4
1.5 RESEARCH METHODOLOGY	5
1.5.1 Demarcation and scope of the study	5
1.5.2 Design of the study and modes of enquiry	5
1.5.3 Research tool for the investigation	5
1.5.4 The study population	6
1.5.5 Ethical considerations	6
1.6 VALIDITY AND RELIABILITY	7
1.6.1 Validity	7
1.6.2 Reliability	7
1.7 SIGNIFICANCE AND VALUE OF THE STUDY	7
1.8 IMPLEMENTATION OF THE FINDINGS	8
1.9 ARRANGEMENT OF THE REPORT	8
1.10 CONCLUSION	9
CHAPTER 2: LITERATURE REVIEW	10
2.1 INTRODUCTION	10
2.2 CONCEPTUAL FRAMEWORK	11
2.2.1 The anatomy of the abdomen of paediatric patients	13
2.2.2 Nephroblastoma (Wilm's tumour)	14
2.2.3 Computed tomography	15
2.2.4 Optimisation in radiation protection	18
2.2.5 Development of diagnostic reference levels	19

2.2.6	Considerations when compiling paediatric diagnostic reference levels for computed tomography examinations.....	25
2.2.7	Paediatrics diagnostic reference levels on computed tomography abdominal examination	29
2.2.8	Benefits of calculating clinical DRL values for paediatric patients.....	33
2.3	CONCLUSION.....	33
	CHAPTER 3: METHODOLOGY.....	35
3.1	INTRODUCTION	35
3.2	RESEARCH DESIGN, MATERIALS AND METHODS	35
3.2.1	Research approach.....	35
3.2.2	Research design	36
3.2.3	Research tool.....	36
3.2.4	Pilot study	37
3.2.5	Target population.....	37
3.2.6	Sample strategy and size	38
3.2.7	Inclusion and exclusion criteria.....	40
3.3	DATA GATHERING	41
3.4	DATA ANALYSIS.....	42
3.5	VALIDITY AND RELIABILITY OF THE DATA RECORDING DOCUMENT	43
3.5.1	Reliability.....	43
3.5.2	Validity.....	44
3.6	ETHICAL CONSIDERATIONS	44
3.6.1	Ethical approval.....	44
3.6.2	Informed consent.....	44
3.6.3	Participant withdrawal	45
3.6.4	Participant/Patient safety	45
3.6.5	Financial implications	45
3.6.6	Right of privacy.....	45
3.7	CONCLUSION.....	46
	CHAPTER 4: RESULTS AND DISCUSSION.....	47
4.1	INTRODUCTION	47
4.2	RESULTS OF THE RESEARCH STUDY	47
4.2.1	Computed tomography unit.....	47
4.2.2	Computed tomography examination	48
4.2.3	Demographics of sample size.....	49
4.2.4	Diagnostic reference levels according to patient age.....	52
4.2.5	Diagnostic reference levels according to patient weight.....	59

4.2.6	Diagnostic reference levels according to the patient's effective diameter 64	
4.2.7	Comparison of diagnostic reference levels - weight versus effective diameter.....	70
4.2.8	Diagnostic reference levels for the whole sample size	71
4.2.9	The diagnostic reference levels in this study in relation to diagnostic reference levels developed in other studies	73
4.3	DISCUSSION	78
4.3.1	Diagnostic reference levels according to age	81
4.3.2	Diagnostic reference levels according to weight	83
4.3.3	Diagnostic reference levels according to the effective diameter	84
4.3.4	Comparison of diagnostic reference levels- weight versus the effective diameter.....	85
4.3.5	Diagnostic reference levels for the whole sample size	86
4.4	CONCLUSION.....	89
	CHAPTER 5: CONCLUSION, RECOMMENDATIONS AND LIMITATIONS	90
5.1	INTRODUCTION	90
5.2	OVERVIEW OF THE RESEARCH STUDY.....	90
5.2.1	Research question and objectives	90
5.3	CONCLUSION.....	92
5.4	LIMITATIONS OF THE RESEARCH STUDY	94
5.5	CONTRIBUTION OF THE RESEARCH.....	95
5.6	RECOMMENDATIONS.....	95
5.7	CONCLUSIVE REMARKS	96
	REFERENCES.....	98
	APPENDICES	108
	APPENDIX A- DATA RECORDING DOCUMENT.....	109
	APPENDIX B- ETHICAL APPROVAL OBTAINED FROM HSREC	110
	APPENDIX C- APPROVAL LETTER- FREE STATE DEPARTMENT OF HEALTH	111
	APPENDIX D- PERMISSION LETTER FROM THE IMAGING DEPARTMENT	112
	APPENDIX E- LETTER FROM BIOSTATISTICIAN.....	114
	APPENDIX F- LETTER FROM LANGUAGE EDITOR.....	115
	APPENDIX G- TURNITIN REPORT	117

GLOSSARY OF TERMS

Anterior-posterior (AP) dimension: The anterior-posterior (AP) dimension is defined as the measurement of the thickness of the body part being scanned from its anterior to posterior aspects. Physical calipers and electronic calipers of the computed tomography (CT) can both be used to obtain the AP dimension directly from the patient and on the image (American Association of Physicists in Medicine (AAPM), 2011:3).

Clinical indication: Clinical indication is a valid reason to use medication for medical matters, such as signs/symptoms or diseases/disorders (Sohn & Liu, 2014:1046).

Contrast media: Contrast media is also called contrast agents, that are used in radiology to enhance the visualisation of certain body structures subjected to analysis in a medical image (Alshowiman, Sahrah, Alswailem, Alotaibi, Altowaijiri & Alghathami, 2021:156).

Contrast-enhanced: Contrast-enhanced refer to iodinated contrast media that have been administrated into a patient's bloodstream intravenously during the scanning procedure (SCP radiology, 2025: online).

Diagnostic reference level (DRL): Diagnostic reference level is an investigation level used for the optimisation of protection in medical exposure during diagnostic and interventional procedures (International Commission on Radiological Protection (ICRP), 2017:13).

DRL quantity: Diagnostic reference level (DRL) quantity is a radiation metric that is commonly calculated or measured to determine how much ionising radiation is used to carry out medical imaging procedures (International Commission on Radiological Protection (ICRP), 2017:21).

DRL value: A DRL value is an estimated value, set at the 75th percentile of the distribution of medians in a healthcare facility or across multiple healthcare facilities in a country (ICRP, 2017:21).

Dose length product (DLP): The DLP is a product of volume CT dose index (CTDI_{vol}) and scan length (cm), which is proportional to the total ionising energy (American Association of Physicists in Medicine (AAPM), 2011:1).

Effective diameter: The effective diameter is calculated using a circular cross-section of the patient when a given location on its z-axis is analysed (AAPM, 2011:4).

Lateral (LAT) dimension: The lateral (LAT) dimension measures the size of the body part being scanned from side to side. Physical calipers and/or electronic calipers of the CT unit can be used to obtain lateral dimension directly from the patient (physical parameter) or on the CT image using the electronic calipers (AAPM, 2011:3).

Local diagnostic reference level (LDRL): Local diagnostic reference level is determined by the third quartile (the 75th percentile) of the distribution of patient doses, for a defined imaging task collected from selected radiology departments in a large healthcare institution or group of healthcare facilities, grouped according to standardised patient characteristics (European Commission (EC), 2018:14).

National diagnostic reference level (NDRL): National diagnostic reference level is calculated as the third quartile (75th percentile) of the median distribution of patient doses obtained from a representative sample of radiology departments in a country, for a defined clinical imaging task survey based on standardised patient groupings (EC, 2018:15).

Nephroblastoma: Nephroblastoma is a type of kidney cancer usually seen in children and only rarely in adults (Poole, 2010:324). Nephroblastoma tumours are considered to be malignant since they develop rapidly and metastasise early (Yiallourous, 2017:3).

Optimisation of protection: Optimisation of protection means keeping the magnitude of individual doses, number of people exposed, and potential risk for exposure below the appropriate dose constraints, while incorporating economic and social factors (ICRP, 2007:23).

Size-specific dose estimate (SSDE): The size-specific dose estimate (SSDE) estimates the dose for CT scans based on linear dimensions measured on or determined from the patient or based on the patient's image, using patient size corrections (AAPM, 2011:19).

Sum of the AP and lateral (LAT) dimensions: The sum of the AP and LAT dimensions demonstrates a linear correlation with the effective diameter in an analysis conducted in AAPM report No. 204 (AAPM, 2011:4).

Typical DRL: A typical DRL is an indication of the median data distribution for a DRL quantity in a clinical procedure (ICRP, 2017:26).

Volume computed tomography dose index (CTDI_{vol}): The volume computed tomography dose index (CTDI_{vol}) represents the overall absorbed radiation dose received across x, y and z directions (Bolowia, 2018:2) and is measured in milligray (mGy) (Nyathi & Shivambu, 2019:350).

LIST OF ACRONYMS AND ABBREVIATIONS

AAPM:	American Association of Physicists in Medicine
AEC:	automated exposure control
ALARA:	as low as reasonably achievable
AP:	anterior-posterior
ASIR:	adaptive statistical iterative reconstruction
ATCM:	automated tube current modulation
BMI:	Body mass index
cm:	centimetre
CNR:	contrast-to-noise ratio
CT:	computed tomography
CTDI _{vol} :	volume computed tomography dose index
D _{eff} :	effective diameter
DICOM:	Digital Imaging and Communication in Medicine
DLP:	dose length product
DoH:	Department of Health
DRL:	diagnostic reference level
EC:	European Commission
FBP:	filtered back projection
GE:	General Electric
HSREC:	Health Sciences Research Ethics Committee
I:	iodine
ICRP:	International Commission on Radiological Protection

I/mL:	Iodine per millilitre
IQR:	interquartile range
IR:	iterative reconstruction
kg:	kilogram
kV:	kilovoltage
kVp:	kilovoltage peak
LAT:	lateral
LDRL:	local diagnostic reference level
mA:	milliampere
mAs:	milliampere-seconds
mg:	milligram
mGy:	milligray
mGy.cm:	milligray per centimetre
mL:	millilitre
mm:	millimetre
n:	number
N/A:	not available
NDRL:	national diagnostic reference level
N/I:	not indicated
NS:	not significant
PACS:	Picture Archiving and Communication System
POPIA:	Protection of personal information act
QC:	Quality control
RDRL:	regional diagnostic reference level

S: significant

SAHPRA: South African Health Products Regulatory Authority

SNR: signal-to-noise ratio

SAS: Statistical analysis

SSDE: size-specific dose estimate

LIST OF TABLES

Table 2.1. Imaging protocols for patients with the indication of nephroblastoma at the participating hospital.	16
Table 2.2. Modifiable parameters that directly impact the radiation dose (Zacharias et al., 2013:952).	16
Table 2.3. Paediatric Diagnostic Reference Levels developed for CT abdomen by various authors.	28
Table 2.4. Clinical-indicated DRL values for paediatric CT abdomen examination.	30
Table 4.1. Computed tomography unit specifications and quality control test dates.	49
Table 4.2. Shapiro-Wilk test results performed on the dose quantity variables for the age groups.	53
Table 4.3. LDRL values based on the median and the 75 th percentile for the CTDI _{vol} , DLP, SSDE _{AP} Dimension, SSDE _{LAT} Dimension, SSDE _{SUM} Dimension and SSDE _{Effective Diameter} for age groups.	54
Table 4.4. Spearman correlation coefficient (r) and p-value for all study variables for age groups.	55
Table 4.5. Spearman correlation coefficient (r) and p-value comparing all dose quantities in all age groups.	57
Table 4.6. The results of the Shapiro-Wilk test performed on the variables for weight groups.	60
Table 4.7. The LDRL values based on the median and the 75 th percentile for the CTDI _{vol} , DLP, SSDE _{AP} Dimension, SSDE _{LAT} , SSDE _{SUM} Dimension, and SSDE _{Effective Diameter} for weight groups.	61
Table 4.8. Spearman correlation coefficient (r) and p-value for all study variables for weight groups.	62
Table 4.9. Spearman correlation coefficient (r) and p-value comparing all dose quantities in all weight groups.	64

Table 4.10. Results of the Shapiro-Wilk test performed on the variables for effective diameter groups. 66

Table 4.11. The LDRL values based on the median and the 75th percentile for the CTDI_{vol}, DLP, SSDE_{AP} Dimension, SSDE_{LAT}, SSDE_{SUM} Dimension, and SSDE_{Effective Diameter} for two effective diameter groups. 67

Table 4.12. The results of the Spearman correlation coefficient (r) and the p-value (p) calculations performed on the variables for the effective diameter groups. 68

Table 4.13. Spearman correlation coefficient (r) and p-value, comparing all dose quantities for two effective diameter groups. 70

Table 4.14. Comparison of paediatric LDRL values based on the median and the 75th percentile calculated, using weight versus effective diameter of the patient. 72

Table 4.15. LDRL values based on the median and the 75th percentile for the CTDI_{vol}, DLP, SSDE_{AP} Dimension, SSDE_{LAT} Dimension, SSDE_{SUM} Dimension and SSDE_{Effective Diameter} for the whole study sample (n = 120). 73

Table 4.16. The confidence limits for comparison of the 75th percentile of CTDI_{vol} and SSDE parameters for the whole sample size (n = 120). 74

Table 4.17. Spearman correlation coefficient (r) and p-value between patient age and weight for the whole study sample (n = 120). 74

Table 4.18. Comparison of the LDRL values based on the median and the 75th percentile of this research study, with published studies for CT abdomen-pelvis examinations for paediatric patients. 76

LIST OF FIGURES

Figure 2.1. Diagrammatic overview of the theoretical framework.	12
Figure 2.2. Anatomy of a paediatric abdomen.	13
Figure 2.3. Nephroblastoma visible on an axial CT image.	14
Figure 2.4. The illustration of a dose report on the PACS for a CT abdomen-pelvis examination at the participating hospital (PACS, 2022).	20
Figure 2.5. Demonstration of an axial CT slice with AP (orange line) and LAT (blue line) dimensions.	24
Figure 3.1. Illustration of the stratified sampling technique, used for this study, to select the participants for each category.	39
Figure 3.2. Illustration of the grouping for effective diameter.	40
Figure 4.1. Weight group categories and frequency of patients (n = 120).	51
Figure 4.2. Age group categories and frequency of patients (n = 120).	51
Figure 4.3. Effective diameter group categories and frequency of patients (n = 120).	52

LIST OF EQUATIONS

Equation 1: The equation used at the imaging department to convert weight into contrast volume.	22
Equation 2: The equation used to convert contrast injected into weight.	22
Equation 3: The equation used to calculate SSDE as suggested by the AAPM Task Group Report No. 204.	23
Equation 4: An example of how Equation 2 was used to calculate D_{eff} as suggested by the AAPM Task Group Report No. 204.	25

CHAPTER 1: INTRODUCTION AND BACKGROUND

1.1 INTRODUCTION

Computed tomography (CT) was presented to clinical practice during the 1970s. In recent years, a CT scan has become an increasingly common technique to diagnose diseases (Parsi, Sohrabi, Mianji & Paydar, 2018:273). Computed tomography has become essential to paediatric radiology with the ongoing technological developments, being established as an important part of the diagnostic procedure (Hojreh, Weber & Homolka, 2015:1574). As a lifesaving approach, CT is essential in paediatric medicine as it is the golden standard for detecting and managing many diseases (Afzalipour, Abdollahi, Hajjalizadeh, Jafari & Mahdavi, 2019:415). In a study conducted by Shibata, Shibamoto, Maehara, Hobo, Hotta and Ozawa (2020:2), it was found that paediatric patients often undergo CT screenings for diseases such as neuroblastoma, soft tissue sarcoma, lymphoma, and skeletal anomalies. However, paediatric CT poses a particular concern since paediatric patients have a higher risk from radiation (Järvinen, Seuri, Kortensniemi, Lanjunen, Hallinen, Savikurki-Heikkilä, Laarne, Perhomaa & Tyrväinen, 2015:86). The epidemiological studies have shown an increased cancer risk associated with CT examinations (Järvinen et al. 2015:86). As stated by Muhammad, Abdul Karim, Abu Hassan, Ahmad Kamarudin, Ding Wong and Ng (2020:2), the use a CT scan has previously led to severe deterministic, as well as stochastic effects, due to sub-optimal scanning protocols. Hence, it is important to pay attention to the justification and optimisation of paediatric CT examinations (Järvinen et al., 2015:87). The basis of optimisation is that of developing diagnostic reference level (DRL) values (Saravanakumar, Vaideki, Goovindarajan, Devenand, Jayakumar & Sharma, 2016:342).

The International Commission on Radiological Protection (ICRP) first proposed DRL values in 1996 and subsequently introduced them into European and Irish legislation (Saravanakumar et al., 2016:342). The ICRP describes DRL values as a form of investigation levels applied to an easily measured quantity (Saravanakumar et al., 2016:342). In practice, DRL values are recommended levels that an imaging facility should use to examine its methods, and determine if acceptable image quality can be

attained at lower doses (Habib Geryes, Hornbeck, Jarrige, Pierrat, Ducou Le Pointe & Dreuil, 2019:19). When a DRL value has been exceeded for any procedure, an investigation should be conducted as soon as possible to determine the possible causes for exceeding a DRL value (ICRP, 2017:121). In addition, the ICRP (2017:31) indicated that DRL values are not dose limits and are not based on individual patients but rather on a specific group of patients.

Computed tomography utilises dose indicators, such as volume computed tomography dose index ($CTDI_{vol}$) and dose length product (DLP) as DRL quantities (European Commission (EC), 2018:32). Most CT consoles display the $CTDI_{vol}$ and DLP for a particular patient's CT scan, based on the reference phantom selected by the scanner. The reference phantom size does not take into account the size differences between children and adults (ICRP, 2017:96). The American Association of Physicists in Medicine (AAPM) developed a new dose estimate of CT exposure, namely size-specific dose estimates (SSDE), which takes into consideration the patient's body size (Imai, Miyazaki, Horiuchi, Kurosawa & Nosaka, 2015:346). Dose estimates based on the patient's size are considered more precise; therefore, they should be used when the size of a patient is available (ICRP, 2017:97). In addition, different clinical indications for an examination may need different image qualities, and consequently, different amounts of radiation (ICRP, 2017:32). Therefore, setting DRL values without considering the clinical indication has little significance (ICRP, 2017:33).

A literature search was conducted to find paediatric local DRL (LDRL) values developed for CT examinations in South Africa. The most recent paediatric LDRL values were found in the study titled "An audit of radiation doses received by paediatric patients undergoing computed tomography investigations at academic hospitals in South Africa," conducted by Van der Merwe and Mahomed (2020). They used the $CTDI_{vol}$, DLP and patient age to develop LDRL values for CT brain, CT temporal bones, CT cervical spine, CT trunk, CT chest and CT abdomen at two university hospitals. Other paediatric LDRL values were found in a study conducted by Vawda (2017) titled "Diagnostic reference levels for paediatric computed tomography". Vawda (2017) used the $CTDI_{vol}$ and DLP to develop paediatric LDRL values for emergency

paediatric head CT scans based on the patient's age at a South African tertiary-level hospital. However, paediatric CT LDRL values established, based on clinical indications and the size of patients in South Africa, do not yet exist. Therefore, this study was performed to develop paediatric LDRL values based on the SSDE and the most common clinical indications for contrast-enhanced abdominal CT examinations at the participating hospital.

1.2 BACKGROUND TO THE STUDY

A literature search was conducted to find similar studies where paediatric LDRL values are developed based on a specific clinical indication with age, weight and effective diameter linked for categorisation. The electronic search was conducted using search engines such as Google Scholar and academic data bases such as EBSCOhost, PubMed, Science Direct, and ProQuest. The research study conducted by Järvinen et al. (2015) used the patient's weight linked with age to develop LDRL values based on different clinical indications by analysing 1,049 paediatric patients' CT scans at four university hospitals. Järvinen et al. (2015) used the $CTDI_{vol}$, DLP, age and weight to develop LDRL values for four CT examinations (CT chest, CT abdomen, CT head, and CT chest, and abdomen) and four clinical indications (tumour, infection, trauma, and angiography). The study of Hwang, Choi, Yoon, Ryu, Shin, Kim, Lee, You and Park (2021) used SSDE to develop paediatric DRLs for age groups, weight groups and effective diameter groups. Satharasinghe, Jeyasugiththan, Wanninayake, Pallewatte and Samarasinghe (2022) also used SSDE for age groups and effective diameter groups, whereas the study of Imai et al. (2015) only used SSDE for age groups. Despite the use of SSDE by Hwang et al. (2021), Satharasinghe et al. (2022) and Imai et al. (2015), no paediatric DRL values for nephroblastoma have been identified. Clinical indications in these studies do not include nephroblastoma. It was found through a literature evaluation that no documented paediatric LDRL values existed for CT examinations to investigate and stage nephroblastoma in South Africa. Moreover, currently, no studies have been found where paediatric LDRL values were developed based on clinical indication and SSDE.

1.3 PROBLEM STATEMENT AND RESEARCH QUESTIONS

1.3.1 Problem statement

Nephroblastoma was reportedly the most common clinical indication for paediatric patients when they present for abdominal CT examinations at the participating hospital (Lesetja, 2021). Furthermore, the use of CT is known to increase cancer risk over a child's lifetime since children's organs and tissues are inherently more prone to cellular damage than adults (Järvinen et al. 2015:86). Therefore, the absence of established clinical indication-based paediatric LDRL values in South Africa limits the ability to identify unusually high dose levels and ensure optimal radiation protection during contrast-enhanced abdominal CT examinations of paediatric patients who present with nephroblastoma.

1.3.2 Research question

What are the paediatric LDRL values for contrast-enhanced abdominal CT examinations for nephroblastoma cases to ensure optimised radiation usage?

1.4 AIM AND OBJECTIVES OF THE STUDY

1.4.1 AIM OF THE STUDY

The aim of the study was to establish paediatric LDRL values for contrast-enhanced abdominal CT examinations of paediatric patients who present with nephroblastoma in order to ensure optimised radiation usage.

1.4.2 OBJECTIVES OF THE STUDY

To achieve the aim, the following objectives of the study were pursued:

- To develop paediatric LDRL values that are linked to the patient's weight and age for contrast-enhanced abdominal CT examination for nephroblastoma cases.

- To compare LDRL values calculated using weight versus effective diameter of the patient.
- To compare the clinical indication-based LDRL values with other internationally published clinical indication-based LDRL values.

1.5 RESEARCH METHODOLOGY

This section discusses the methods that were used to establish paediatric LDRL values for contrast-enhanced abdominal CT examinations based on nephroblastoma.

1.5.1 Demarcation and scope of the study

The study was conducted in an academic hospital in Bloemfontein. Data for this study were collected retrospectively from the 8th to the 12th of October, 2022 and also on the 24th of December, 2022.

1.5.2 Design of the study and modes of enquiry

The design of the study was descriptive, in which variables such as the DLP, CTDI_{vol} and SSDE were investigated using a quantitative research approach whereby numerical data was utilised. Data on paediatric patients were collected retrospectively and analysed mathematically.

1.5.3 Research tool for the investigation

Data for this research study were collected through a structured data recording document (Appendix A). The structured data recording document was used to retrospectively capture data, such as the patient's age, CTDI_{vol} and the DLP from the CT dose report. The research tool used for this study will be discussed extensively in Chapter 3 of the dissertation.

1.5.4 The study population

The study population comprised of 265 paediatric patients referred for abdominal CT examinations at the participating hospital 1 January 2018 to 31 December 2021. Paediatric patients who formed part of the study population were scrutinised according to the inclusion and exclusion criteria of the study to form the target population.

1.5.4.1 The target population

In this research study, the target population comprised paediatric patients who presented with nephroblastoma or were suspected of having nephroblastoma (solid mass on the kidneys) for a contrast-enhanced abdominal CT examination at the participating hospital from 1 January 2018 to 31 December 2021.

1.5.4.2 Sample selection and size

Two sampling techniques were used for this study: stratified sampling and purposive sampling. In this study, purposive sampling was used to select the patients, the type of examination, and the clinical indication for which the DRL values needed to be developed. A purposive sampling method was used in this study to develop paediatric LDRL values by using data collected to answer the research question. Stratified sampling was used in this study to randomly select paediatric patients from subgroups according to their age, weight, clinical indication and type of examination to develop DRL values. The sample size of paediatric patients who formed part of this research study is 120 patients for contrast-enhanced abdominal CT examination. The population, sample selection and sample size will be outlined extensively in Chapter 3 of the dissertation.

1.5.5 Ethical considerations

Ethical approval (UFS-HSD2022/0341/3008-0001) was obtained from the Health Sciences Research Ethics Committee (HSREC) at the University of the Free State in Bloemfontein (Appendix B). Permission was also obtained from the Free State Department of Health (DoH) to collect patient information from the CT console, CT

register files and the picture archiving communication system (PACS) at the participating hospital in Bloemfontein (Appendix C). Permission was also obtained from the head of the imaging department at the participating hospital (Appendix D). A more in-depth discussion of the ethical considerations will be outlined in Chapter 3.

1.6 VALIDITY AND RELIABILITY

Validity and reliability involve assessing and reducing the amount of error associated with measurements made using a given research tool (Watson, 2015:45). The validity and reliability of the study were assessed and it is briefly outlined in sections 1.6.1 and 1.6.2, respectively.

1.6.1 Validity

Validity is defined as the degree to which a measurement made by the research tool accurately reflects the researcher's interests (Watson, 2015:45). Validity was ensured through the pilot study conducted before the main study. Moreover, the content validity of the structured data recording document was safeguarded because the research tool was obtained from the publication of Public Health England (2014) and adjusted according to this research study.

1.6.2 Reliability

The reliability of a tool is measured by its ability to measure the same value every time (Watson, 2015:45). A structured data recording document used in this research study was designed to give the same results every time it was used. The reliability was assessed by observing the same measurements more than once and calculating the correlation of their difference. In addition, a pilot study was performed to ensure the reliability of the data recording document.

1.7 SIGNIFICANCE AND VALUE OF THE STUDY

The end result of this study is the development of clinical, indication-based LDRL values that can be used as a tool to optimise and monitor the radiation dose received

by paediatric patients who present with nephroblastoma for contrast-enhanced abdominal CT examinations. The established LDRL values in this study will contribute as a guide to optimise the radiation dose received by paediatric patients presenting with nephroblastoma for CT abdomen examination.

1.8 IMPLEMENTATION OF THE FINDINGS

The methods that were used for the study will be presented to the imaging department, where radiographers will be equipped to assist the medical physicist in developing LDRL values for the imaging department at the participating hospital.

1.9 ARRANGEMENT OF THE REPORT

The dissertation is arranged in five chapters. Each chapter comprises the following content:

Chapter 1: Introduction and background provides the background of the study relating to establishing paediatric LDRL values for contrast-enhanced abdominal CT examination based on nephroblastoma. The aim, objectives, and methodology of the study are briefly discussed. The value of the study is also highlighted in this chapter.

Chapter 2: Literature review discusses context information concerning different elements that contribute to establishing paediatric LDRL values for contrast-enhanced abdominal CT examination based on nephroblastoma while considering the age, weight, effective diameter and dose metrics, such as the SSDE.

Chapter 3: Methodology discusses the methods that were followed when conducting the study. The methodology of the study elaborates on how the data were collected, analysed and how the patient data were protected. Furthermore, this chapter elaborates on the ethical principles adhered to in this study.

Chapter 4: Results and discussion focuses on the conclusions gathered from the analysed data and reports on the established LDRL values based on the age, weight

and effective diameter of the patient for the different dose quantities for nephroblastoma.

Chapter 5: Conclusion, recommendations and limitations supplies a summary of the main points of the study. The conclusion and recommendations of the study are presented in this chapter. Furthermore, the limitations and weak areas of the study are discussed based on factors that could not be controlled when the study was conducted.

1.10 CONCLUSION

Chapter 1 provided the background of the study, relating to the establishment of paediatric LDRL values based on the clinical indication for CT examinations and the size of the patient (SSDE). The chapter clearly showed no documented paediatric LDRL values developed based on nephroblastoma for contrast-enhanced CT abdominal examinations in South Africa. Internationally, no studies were found where paediatric DRL values were developed based on the clinical indication and the SSDE for CT examinations. Therefore, the aim of this research study was to establish paediatric LDRL values for contrast-enhanced abdominal CT examinations for nephroblastoma based on the size of the patients. In this study, the established DRL values will serve as a guide to optimising the radiation dose for paediatric patients with nephroblastoma undergoing CT abdomen imaging.

Chapter 2, entitled *Literature review*, will discuss the context information on the different elements that contribute to establishing paediatric LDRL values for contrast-enhanced abdominal CT examination based on nephroblastoma with age, weight and the effective diameter as categorising groups. The different dose quantities and how the SSDE can be used to establish DRL values will be discussed. Moreover, aspects relating to CT imaging and the importance of quality control will also be outlined.

CHAPTER 2: LITERATURE REVIEW

2.1 INTRODUCTION

Computed tomography (CT) uses more radiation dose than the typical conventional X-ray imaging methods (Ogbole, 2010:118). A CT scan delivers a significantly higher radiation dose and cancer risk than alternative imaging methods, particularly in children (Almohiy, 2014:1). Computed tomography uses an entirely different radiation dose distribution from general radiography as a result of the distinctive way radiation dose is deposited (Ogbole, 2010:119). Comparing CT to X-ray projection imaging, CT has a higher radiation dose due to the following reasons: high collimation is used to obtain a single CT image, irradiated tissue is exposed to X-rays almost from all directions, and a high signal-to-noise ratio (SNR) is required for CT acquisition to achieve high contrast resolution (Ogbole, 2010:119). Computed tomography use is known to increase cancer risk over a child's lifetime since children's organs and tissues are inherently more prone to cellular damage than adults (Almohiy, 2014:1). The radiation dose received by children during routine CT scans is much higher than is necessary, which can lead to fatal cancer cases in children (Zacharias, Alessio, Otto, Iyer, Philips, Swanson & Thapa, 2013:951). Hence, this study was necessary to develop paediatric LDRL values to optimise the radiation dose received by paediatric patients who present with nephroblastoma for contrast-enhanced CT abdomen. Saravanakumar et al. (2016:342) also stated that the development of DRL values is the basis of radiation dose optimisation, which supports the aim of this study.

In Chapter 1, the background of the study and the significance of establishing paediatric LDRL values for contrast-enhanced abdominal CT examination based on nephroblastoma were discussed. The aim and value of the study were also highlighted in this chapter. In Chapter 2, context information on the different elements that contribute to establishing paediatric LDRL values for contrast-enhanced abdominal CT examinations based on the clinical history of nephroblastoma, using SSDE methods and age, weight with effective diameter for categorising, will be discussed. A theoretical framework was developed, and elements, such as CT dose quantities, clinical indication (nephroblastoma), SSDE, paediatric DRL values, paediatric anatomy, and clinical protocols will be discussed in greater depth.

2.2 CONCEPTUAL FRAMEWORK

The principle of ALARA (as low as reasonably achievable) has been used as a guide for radiation protection measures in recent years (Lampignano & Kendrick, 2014:59). Brady, Ramanauskas, Cain and Johnston (2012:1488) stated that ionising radiation in medical procedures must be justified and optimised. The optimisation of paediatric imaging is particularly important because of the higher risk of radiation-related harmful effects in children and the longer lifespan during which these effects may manifest (ICRP, 2017:92). It is crucial to prioritise optimisation efforts based on the potential risk of stochastic effects in patients. The ICRP recommends DRL values as a measure to improve optimisation by identifying high patient dose levels that may not be justified in terms of image quality (Järvinen et al., 2015:86). Hence, this study aimed to optimise paediatric dose levels by developing paediatric LDRL values for contrast-enhanced abdominal CT examinations based on the clinical history of nephroblastoma.

The concept framework defines the relevant objectives of the research process, as well as the mechanism by which they will be combined to form coherent conclusions (Swaen & George, 2024). Figure 2.1 is a diagrammatic overview of the conceptual framework for this study.

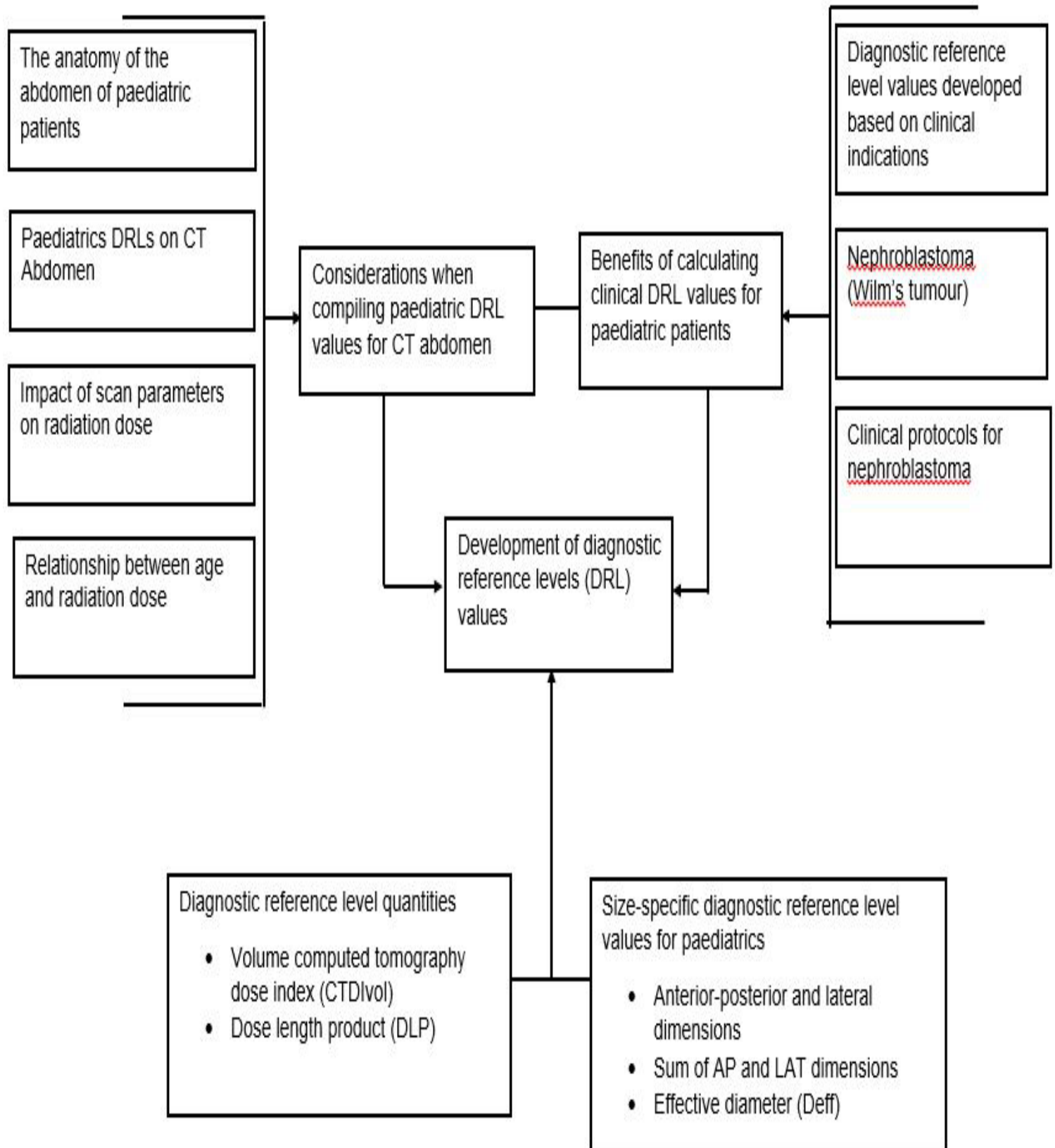


Figure 2.1. Diagrammatic overview of the conceptual framework (compiled by the researcher, Tebello Pitso, 2024).

2.2.1 The anatomy of the abdomen of paediatric patients

The surface anatomy differs according to demographic factors, such as age and body mass index (BMI) (Şener, Tellioglu & Polat, 2022:178). Understanding the anatomical differences between adults and paediatrics is crucial for managing paediatrics (Lander & Newman, 2013:101). Adults have a rectangular abdomen with vertical long axes, while a paediatric's abdomen is broader than it is long (Lander & Newman, 2013:102). A paediatric stomach has a relatively small capacity at birth, with a volume of approximately 30 millilitres (mL) and is located under the liver, as seen in Figure 2.2 (Lander & Newman, 2013:102). In younger paediatrics, the kidneys are substantially smaller (Subramaniam, Taghavi & Mirjalili, 2016:199). The left kidney is posteriorly linked to the 11th and 12th ribs, while the right kidney is linked only to the 12th rib (Subramaniam et al., 2016:199). Compared to adults, the small intestine has fewer and less prominent circular folds (Lander & Newman, 2013:102). The liver is quite large in paediatrics, accounting for 4% of body weight compared to adults, contributing to only 2.5 to 3% (Lander & Newman, 2013:102). Various pathologies may develop in the abdomen, such as nephroblastoma.

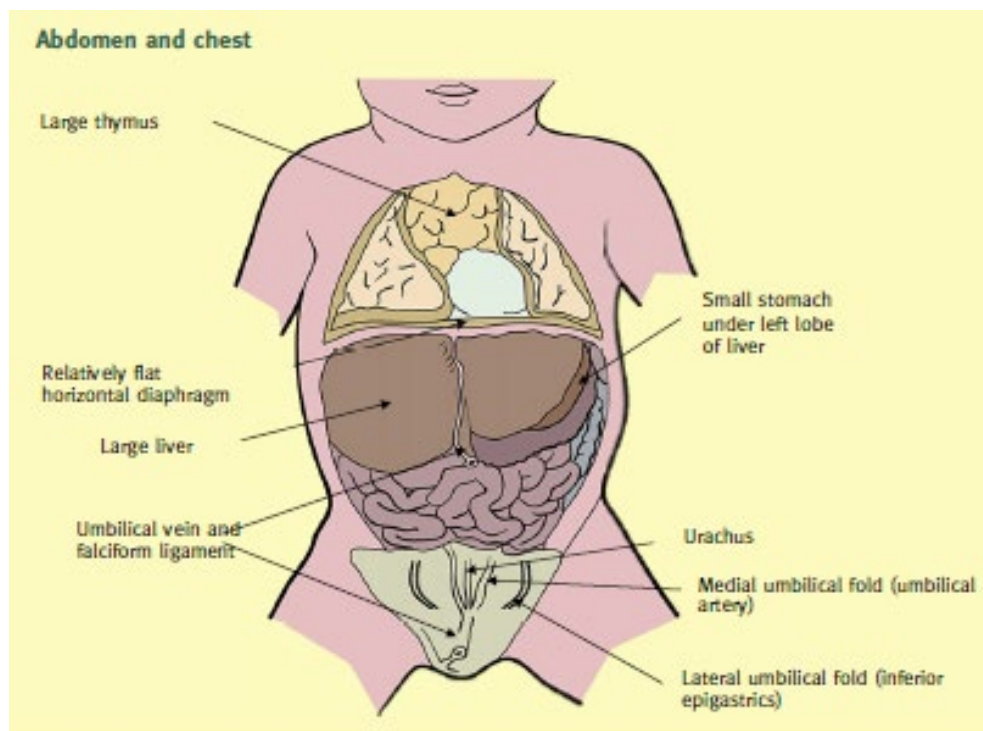


Figure 2.2. Anatomy of a paediatric abdomen (Lander & Newman, 2013:102).

2.2.2 Nephroblastoma (Wilm's tumour)

Nephroblastoma is a type of kidney cancer usually seen in children and rarely in adults (Poole, 2010:324). Nephroblastoma tumours are considered malignant since they develop fast and metastasise early (Yiallourous, 2017:3). Varan (2008:84) stated that nephroblastoma is prevalent in children between one and five years of age and represents 5.9% of all malignant tumours in childhood. For the definitive diagnosis of nephroblastoma, imaging procedures, such as abdominal ultrasounds, magnetic resonance imaging (MRI), and CT scans, are crucial and recommended (Yiallourous, 2017:5). Poole (2010:325) also reported that the contrast intravenous pyelogram had been largely replaced by abdominal CT scanning to detect nephroblastoma (see Figure 2.3). Nephroblastoma is accurately diagnosed by performing a CT abdomen-pelvis protocol in the portal venous phase with the injection of contrast media (Foster, 2023: online). Omnipaque 300 milligrams of Iodine per millilitre (I/mL) iodinated contrast media is used for contrast-enhanced abdominal CT examination at the participating hospital of this research study to detect nephroblastoma. Ultrasound, MRI, and CT are the modalities used to determine tumour size, differentiate nephroblastoma from other kidney tumours, and determine if the tumour has spread (Yiallourous, 2017:5).



Figure 2.3. Nephroblastoma (red arrow) visible on an axial CT image (personal communication; J Janse van Rensburg, 2022; JanseVRJ@ufs.ac.za).

2.2.3 Computed tomography

Computed tomography scan is a computerised X-ray imaging technique that uses a narrow beam of X-rays to create cross-sectional images of a patient's anatomy (National Institute of Biomedical Imaging and Bioengineering, 2022: online). The first applications of CT in clinical practice date back to the 1970s. Computed tomography scans have become increasingly common for diagnosing diseases over the past few years (Parsi et al., 2018:273). Owing to suboptimal scanning protocols, CT scans have previously resulted in severe deterministic and stochastic effects (Muhammad et al., 2020:2). It is, therefore, imperative to consider the justification and optimisation of paediatric CT examinations (Järvinen et al., 2015:87).

2.2.3.1 *Computed tomography clinical protocols for nephroblastoma*

Nephroblastoma is the most common solid renal mass and abdominal malignancy presenting during childhood (Khan, 2023: online). Clinical presentation of nephroblastoma often comprises a painless upper quadrant abdominal mass (Foster, 2023: online). However, other signs and symptoms could include hematuria, hypertension and von Willebrand disease (Foster, 2023: online). The American College of Radiology (2021:2) listed adrenal mass as one of the indications of a CT abdomen-pelvis protocol. Computed tomography abdomen-pelvis protocol is performed in the portal venous phase, with the injection of contrast media sufficient to characterise nephroblastoma (Foster, 2023: online).

Computed tomography abdomen-pelvis protocol serves as a framework for examining the entire abdomen, including the pelvis (Feger, Campos & Murphy, 2023: online). Two protocols are used for patients of different sizes at the participating hospital. Both protocols are performed in the portal venous phase to characterise nephroblastoma. Table 2.1 summarises the two protocols used for patients with the indication of nephroblastoma. The study by Otto, Janse Van Rensburg and Stones (2015:2) revealed that patients with high-risk nephroblastoma may get up to eight CT abdomen-pelvis scans throughout the post-treatment follow-up period. Computed tomography is also useful for identifying lymph node enlargement, which could be tumour metastases or reactive changes (Adegboyega, Osuoji, Akinola, Balogun, Fatureti & Awosanya, 2014:34).

Table 2.1. Imaging protocols for patients with the indication of nephroblastoma at the participating hospital.

Recon	Body part	kV	mA	Thickness/ spacing	Pitch	Algorithm	Recon destination	Rotation time (sec)
1	IV abdomen/ pelvis	100 kV	120–450 mA	5 mm × 5 mm	0.97	Standard	PACS	0.5 sec
2	Thin abdomen/ pelvis	100 kV	120–450 mA	6 mm × 6 mm	0.53	Standard	PACS	0.5 sec

IV: intravenous, kV: kilovoltage, mA: milliampere, PACS: picture archiving and communication system, Sec: seconds

2.2.3.2 Impact of scan parameters on radiation dose

Several scanning parameters can be modified and have a direct impact on radiation dose, including kilovoltage peak (kVp), milliampere-seconds (mAs), gantry rotation time, section thickness, pitch, distance travelled during a 360° rotation of the gantry, X-ray tube to the CT isocenter, and the scan length (see Table 2.2) (Zacharias et al., 2013:952).

Table 2.2. Modifiable parameters that directly impact the radiation dose (Zacharias et al., 2013:952).

Parameters	Impact on the radiation dose
X-ray beam energy (kVp)	At matched tube current, higher energy increases radiation dose.
Tube current (mAs)	Radiation dose increases with higher tube current.
Gantry rotation	A faster gantry rotation reduces radiation dose.
Section thickness	Radiation dose increases with thinner collimation.
Pitch	A higher pitch reduces radiation dose at a matched tube current.
Distance of the X-ray tube to the CT isocenter	Radiation dose is decreased with optimal patient placement (isocenter).
Scan length	The radiation dose increases as the scan range is extended.

A nonlinear relationship exists between the beam energy and radiation dose (Zacharias et al., 2013:953). A decrease in kVp causes an exponential increase in image noise, which often necessitates a rise in mAs to maintain good image quality (Raman et al., Mahesh, Blasko & Fishman, 2013:842). Radiographers must know how to correctly apply kVp in paediatric imaging since the incorrect adjustment of kVp might result in high noise, which might require high mAs and consequently, higher radiation dose. Radiation dose and tube current are linearly related, meaning that doubling the tube current will result in doubling the radiation dose (Zacharias et al., 2013:953).

Radiation dose and pitch are inversely proportional; scans with a pitch of two give 50% of the radiation dose of scans with a pitch of one (Zacharias et al., 2013:953). The pitch of 0.53 and 0.97 is used when scanning paediatric abdominal CT examinations. As per the explanation of Zacharias et al. (2013:953), the radiation dose to a patient is lower when a pitch of 0.97 was used and higher when a pitch of 0.53 was used. Thus, the higher the pitch, the less dose is used during CT imaging.

Patient placement in relation to the isocenter is also important in reducing radiation dose. Raman et al. (2013:843) found the incorrect centering of phantoms in the scanner gantry to be related to a surface dose increase of 23% and an image noise increase of 7%. Performing CT scans on paediatric patients while incorrectly positioned or improperly centered can result in excessively noisy images with artificially low mAs (Raman et al., 2013:841). Radiographers should be trained to properly position paediatric patients to avoid increased image noise, which might require high mAs adjustments. The paediatric abdominal CT examinations at the participating hospital were done with a thin slice thickness, ranging between 0.63 to 2.5 mm. Section thickness increases CTDI_{vol} values when thinner total beam widths are chosen, while a thin collimated beam requires an overlap of the slices called overbeaming. This impact results in more radiation dose, compared to single-slice scans (Zacharias et al., 2013:953). Since scanning parameters influence radiation dose during CT imaging, one might wonder whether there is a relationship between the age of the patient and the radiation dose.

2.2.3.3 Relationship between age and radiation dose

The patient's age at the time of radiation exposure is a key factor contributing to radiation-induced cancer (Hernández, Terradas, Camps, Martín, Tusell & Genescà, 2015:153). Children exposed to ionising radiation are at higher risk of developing radiation-induced cancer due to the radio-sensitivity of children's organs and longer life expectancy (Almohiy, 2014:1). Abdulkadir, Izge, Yunusa, Mohammed and Osman (2021:3) found that the applied acquisition parameters and dose values increase with increasing patient age. Findings by Abdulkadir et al. (2021) indicate a positive correlation between patient age and radiation dose. These findings were also supported by a study conducted by Brady et al. (2012:1488–1498). According to Brady et al. (2012:1492), the CTDI_{vol} and the DLP increased with patient age in three paediatric examinations (CT head, chest, and abdomen/pelvis). The mAs setting was also increased with paediatric patient age, thus influencing the resulting radiation dose (Abdulkadir et al., 2021:3). Therefore, optimising radiation dose for paediatrics, especially in CT, is crucial.

2.2.4 Optimisation in radiation protection

It has been acknowledged that optimisation of radiation dose is very important and that there is a substantial amount of literature indicating the magnitude of dose reductions that can be achieved through the application of this principle (ICRP, 2007:35). The studies of Järvinen et al. (2015:87) and Saravanakumar et al. (2016:342) clarified the importance of radiation dose optimisation through the development of paediatric DRL values. In radiological protection, there are three main principles: justification, optimisation, and dose limits (ICRP, 2007:1). It is crucial to optimise paediatric imaging, as children are more likely to suffer harmful radiation effects. Some of radiation's health effects on children may include leukemia or solid cancer and thyroid cancer risk (Government of Canada, 2024: online). Furthermore, they have a longer life expectancy, and these effects may become apparent. The ICRP (2007:34) recommends diagnostic reference levels to implement the principle of the optimisation of protection. The use of DRLs are effective tools for enhancing patient protection in medical exposures (ICRP, 2017:29). Therefore, DRL values should be

established for clinical procedures to optimise the radiation dose to paediatric patients (ICRP, 2017:110).

2.2.5 Development of diagnostic reference levels

A diagnostic reference level is a tool used to optimise radiation dose during medical imaging examinations (ICRP, 2017:7). As mentioned previously, paediatric patients have a higher risk of radiation-related effects and a longer lifespan, allowing the effect to manifest (ICRP, 2017:92). Therefore, it is crucial to pay attention to the justification and optimisation of paediatric CT examinations (Järvinen et al., 2015:87).

Local DRL values are set for a group of radiology departments, while DRL values set for a single healthcare facility are known as typical values. Typical values are valuable where a healthcare facility performs large numbers of specialised examinations for which there is no national DRL (ICRP, 2017:46). Local DRL values are determined using the third quartile (the 75th percentile) of the distribution of patient doses for a defined imaging task, collected from selected radiology departments in a large healthcare institution or group of healthcare facilities, grouped according to standardised patient characteristics (EC, 2018:14). Typical values may be derived from the median of the distribution, if an institution lacks sufficient data to use the third quartile (ICRP, 2017:45). Local DRL values or typical values can be set for newer technologies that allow lower dose levels to achieve a similar level of image quality (ICRP, 2017:46). For CT procedures, it is preferable to have at least 20 patients' data within the agreed weight range, if data are collected by means of a paper exercise (ICRP, 2017:39).

2.2.5.1 Diagnostic reference level (DRL) quantities

To calculate DRL values for CT, the dose DRL quantities, CTDI_{vol} and DLP are used (ICRP, 2017:77). Currently, most CT scanners have dose-information software built into their control consoles, as seen in Figure 2.4, which displays both quantities (Bolowia, 2018:2). Considering the accessible collection of the DRL quantities, they are the primary parameters that will be used to determine DRL values in this study. These quantities will be briefly explained.

Dose Report					
Series	Type	Scan Range (mm)	CTDI _{vol} (mGy)	DLP (mGy-cm)	Phantom cm
1	Scout	-	-	-	-
2	Helical	544.240-1327.010	3.37	131.19	Body 32
Total Exam DLP:				131.19	

Figure 2.4. The illustration of a dose report on the PACS for a paediatric CT abdomen-pelvis examination at the participating hospital (personal communication; J Janse van Rensburg, 2022; JanseVRJ@ufs.ac.za).

2.2.5.1.1 Volume computed tomography dose index (CTDI_{vol})

The CTDI_{vol} represents the overall absorbed radiation dose received across a single slice in CT dosimetry phantom (Bolowia, 2018:2) and is measured in milligray (mGy) (Nyathi & Shivambu, 2019:350). The CTDI_{vol} provides an accurate indication of radiation dose for a specific examination protocol, as it accounts for protocol-specific information, such as pitch (Bolowia, 2018:2). The limitation of CTDI_{vol} is that it does not account for the size of the patient and, as a result, cannot provide information about patient doses regarding specific patient sizes (AAPM, 2011:2).

The CTDI_{vol} values are derived from the referencing standard reference phantoms, either 32 cm (body) or 16 cm (head) in diameter (ICRP, 2017:96). The size of the patient has a significant impact on the amount of radiation applied for a procedure but using phantoms does not account for the differences in size between children and adults (ICRP, 2017:96). The CTDI_{vol} must be recorded for each sequence of a respective CT scan, as it may differ for every scan, especially if the automatic tube current modulation (ATCM) is used (ICRP, 2017:81). Using the ATCM can reduce patient dose by 30 to 40% per scan sequence, resulting in a significant reduction of patient dose (ICRP, 2017:81). The CTDI_{vol} for a paediatric body such as the chest, abdomen and chest-abdomen-pelvis, CT protocols are calculated using the 32 cm

diameter phantom as the reference (ICRP, 2017:96). As seen in Figure 2.4, the diameter for the reference phantom is always indicated on the dose report.

2.2.5.1.2 Dose length product (DLP)

The DLP is the product of the $CTDI_{vol}$ and the scan length measured in centimetres (cm) for a specific patient's scan (AAPM, 2011:1). The DLP represents the integrated radiation dose that is accumulated during an entire CT examination (Bolowia, 2018:2). The DLP increases with the scan length; at the same time, the $CTDI_{vol}$ remains unaffected by the patient's scan length (Bolowia, 2018:2). To accurately determine the DLP, the phantom's diameter needs to be known for each specific examination (AAPM, 2011:1). The DLP values are derived from the referencing of standard reference phantoms, either 32 cm (body) or 16 cm (head) in diameter (ICRP, 2017:96). When the ATCM is used during CT imaging, it is recommended that the total number of scan sequences be recorded because it may affect the cumulative DLP (ICRP, 2017:81).

The DLP and $CTDI_{vol}$ are both indices of doses applied to standardised phantoms without considering the patient's size (ICRP, 2017:116). The DLP and $CTDI_{vol}$ are the preferred primary variables because they are readily accessible from the CT console (ICRP, 2017:39). However, calculating DRL values based on the patient's size during CT imaging is valuable. The SSDE is a dose quantity that calculates the DRL based on the patient's size. The SSDE is explained in detail in section 2.2.5.2.

2.2.5.2 Size-specific diagnostic reference levels for paediatrics

The radiation dose that a patient receives from a CT scan is a function of their size and the scanner output (AAPM, 2011:2). Most CT consoles provide the $CTDI_{vol}$ and DLP for a specific patient's CT scan based on the reference phantom selected by the scanner (ICRP, 2017:96). The $CTDI_{vol}$ only provides only information about the scanner's output and does not address patient size; thus, it cannot estimate patient doses (AAPM, 2011:2). The amount of radiation used for examinations of children varies considerably, based on their size and weight (ICRP, 2017:92). Therefore, dose

estimates based on the patient's size are considered to be more precise and should be used when the size of a patient is available (ICRP, 2017:97).

In 2011, the AAPM introduced SSDE for a more precise assessment of patient dose (Mohammadbeigi, Khoshgard, Haghighparast & Eivazi, 2019:1). The SSDE is an estimate of the patient dose that incorporates corrections based on the patient's size, calculated from linear dimensions measured on the patient or a CT image of the patient (AAPM, 2011:18). While the thickness of the body region imaged is the most accurate classification of paediatric patient size, the patient's current weight is the next best alternative if available (ICRP, 2017:97). Therefore, weight-adjusted paediatric DRL values are beneficial for optimisation (ICRP, 2017:92).

Weight is also used to tailor contrast injection protocols to the patient body weight for abdominal and chest examinations (Kessler, Hegenscheid, Fleck, Khaw, Kirsch, Hosten & Langner, 2014:2). The injection of contrast media is tailored to the patient's body weight, and if the weight of a patient is recorded at the participating hospital, then the amount of contrast medium injected is calculated using Equation 1. If the patient's weight is not recorded, the weight is calculated by converting the amount of contrast media (amount of contrast injected $\div$ 1.5 = weight) in the absence of a documented weight of the patient, as illustrated in Equation 2.

For example, if a patient's weight is 15 kg for an abdominal CT examination, the amount of contrast injected for the patient is calculated as follows:

$$\text{Weight} \times 1.5 = \text{amount of contrast injected} \quad (\text{Equation 1})$$

For example, if a patient receives 25 mL for an abdominal CT examination, the weight of the patient is calculated as follows:

$$\text{Weight} = \text{amount of contrast injected} \div 1.5 \quad (\text{Equation 2})$$

$$25 \text{ ml} \div 1.5 = 16.7 \text{ kg}$$

The size-related parameters to calculate the SSDE according to the AAPM (2011:4) are the anterior-posterior (AP) dimension, the lateral (LAT) dimension, the sum of the

AP and LAT dimensions, and the effective diameter (D_{eff}). These size-related parameters will be discussed briefly.

2.2.5.2.1 Anterior-posterior and lateral dimensions

The AP dimension measures the thickness of the body part being scanned from anterior to posterior, while the LAT dimension measures the size of the body part scanned from side to side (AAPM, 2011:3). Electronic calipers can be used to measure the AP and LAT dimension on a conventional CT image which is acquired before the CT scan (AAPM, 2011:3). Analyses conducted in the AAPM Report No. 204 demonstrated a linear correlation between the sum of these two orthogonal dimensions and the D_{eff} (AAPM, 2011:4). The sum of the AP and LAT dimensions is determined by calculating the correlation coefficient between the AP dimension, the effective diameter, and the correlation coefficient between the LAT dimension and the effective diameter. Adding these two parameters results in a linear relationship with the effective diameter, with a correlation coefficient of $r^2 = 0.999$ (AAPM, 2011:15). The sum of the AP and LAT dimensions is used in conjunction with the D_{eff} to determine the conversion factor used to calculate the SSDE.

The AAPM Report No. 204 (AAPM, 2011:4) created a conversion factor for either a 32 cm or 16 cm reference phantom to estimate patient doses. To estimate patient dose, the conversion factor is applied to the displayed CTDI_{vol} to calculate the SSDE. These factors consider the patient's size and are therefore crucial for paediatric CT (AAPM, 2011:2). To calculate the SSDE, Equation 3 from AAPM (2011:2) was used:

$$\text{CTDI}_{\text{vol}} \times \text{conversion factor} = \text{SSDE} \quad (\text{Equation 3})$$

Figure 2.5 is an example of how the AP and LAT dimensions are measured on the CT axial image of a patient. Electronic calipers can be used to measure the AP and LAT dimensions in millimetres (mm) converted into centimetres (cm).

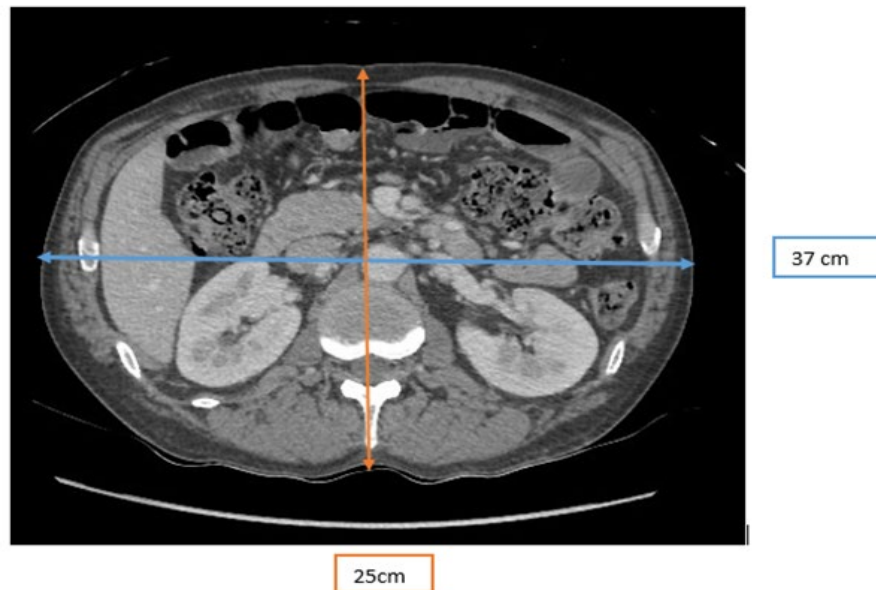


Figure 2.5. Demonstration of an axial CT slice with AP (orange line) and LAT (blue line) dimensions (personal communication; J Janse van Rensburg, 2022; JanseVRJ@ufs.ac.za).

Based on Figure 2.5, the AP dimension is 25 cm, and the LAT dimension is 37 cm. If the sum of the AP and LAT dimensions is used to calculate the SSDE, then the sum is 62 cm. The conversion factor for the sum of 62 cm on the 32 reference phantom is 1.21, according to the AAPM Report No. 204 (2011:10). If the $CTDI_{vol}$ for the abdominal CT examination is 12.03 mGy, then the SSDE is calculated as follows:

$$SSDE = 12.03 (CTDI_{vol}) \times 1.21 (\text{conversion factor}) = 14.56 \text{ mGy}$$

It is important to note that the SSDE for the AP and LAT dimensions was calculated using the same method (Equation 3) discussed above.

2.2.5.2.2 Effective diameter (D_{eff})

The D_{eff} is the diameter of the patient at a given location along the patient's z-axis, assuming that the cross-section of the patient is circular (AAPM, 2011:4). The D_{eff} is calculated from the square root of the product of the patient's AP and LAT dimensions' measurements (ICRP, 2017:97). Equation 4 was used to calculate D_{eff} as suggested by the AAPM Report No. 204 (2011:4):

$$D_{\text{eff}} = \sqrt{(AP \text{ diameter}) \times (LAT \text{ diameter})} \quad (\text{Equation 4})$$

Based on the measurements of the AP and LAT dimensions of Figure 2.5, the D_{eff} is calculated as follows:

$$D_{\text{eff}} = \sqrt{(25 \text{ cm}) \times (37 \text{ cm})}$$

$$D_{\text{eff}} = 30 \text{ cm}$$

If the CTDI_{vol} for the abdominal CT examination is 12.03 mGy, and the conversion factor for 30 cm on a 32 reference phantom is 1.23 (AAPM, 2011:10), the SSDE for the D_{eff} is calculated as follows using Equation 3:

$$12.03 (\text{CTDI}_{\text{vol}}) \times 1.23 (\text{conversion factor}) = 15.64 \text{ mGy (SSDE)}$$

2.2.6 Considerations when compiling paediatric diagnostic reference levels for computed tomography examinations

It is important to have a clear understanding of the equipment's imaging and radiation performance to optimise the radiation dose. This can be accomplished by performing quality control (QC) testing annually on the equipment (ICRP, 2017:47). The QC test was performed on the CT equipment used for this study during the period when the CT abdominal examination was performed on participants involved in this study. The QC tests were performed on 23 October 2018, 24 October 2019, 21 October 2020, 21 October 2021 and 28 October 2022. The results of the QC tests were satisfactory, and the CT machine continued to be used throughout the years.

The ICRP (2017:39) suggests that data from at least 20 to 30 patients should be collected when DRL values are calculated for CT to ensure reasonably accurate results. When DRL values are calculated for different groups/categories, each group should have 20 to 30 patients. Three categorising groups, namely age, weight, and effective diameter, can be used to calculate DRL values (ICRP, 2017:93). This research study excluded age/weight/effective diameter groups with fewer than 20 patients.

The patients were categorised into five age groups, five weight categories and five effective diameter groups, as suggested by the ICRP (2017:93). The grouping of patients according to their *age* was as follows: group 1 [<1 month (M)]; group 2 [1M to <4 years (Y)]; group 3 [4Y to <10 Y]; group 4 [10Y to <14 Y], and group 5 [14Y to <18 Y]. The *weight* was used to group the patients as follows: group 1 [0kg - <5 kg), group 2 [5kg - <15 kg), group 3 [15kg - <30 kg), group 4 [30kg - <50 kg) and group 5 [50 kg to <80 kg). The *effective diameter* groups were as follows: group 1 [<13 cm); group 2 [13 cm to <16 cm); group 3 [16 cm to <20 cm); group 4 [20 cm to <24 cm), and group 5 [<24 cm). The studies of Hwang et al. (2021) and Satharasinghe et al. (2022) also used the effective diameter groups to develop paediatric DRL values. However, the effective diameter groups used in the study of Satharasinghe et al. (2022) are different from those used in this study and in the study by Hwang et al. (2021). This study used the effective diameters approximated from the study of Hwang et al. (2021:1174).

The number of CT scan sequences/scan phases an examination requires depends on its clinical indication. Setting paediatric DRL values without considering the clinical indication has little significance (ICRP, 2017:33). The DRL values should be developed for common examinations and clinical indications with DRL quantities that are easily measurable (Järvinen et al., 2015:86). Therefore, this study included the most common clinical indication, which is nephroblastoma, to calculate paediatric LDRL values for contrast-enhanced abdominal CT examinations. It is important to remember that the number of scan sequences/phases impacts the radiation dose. Single-phase scans result in lower radiation doses than multi-phase scans, which overlap one another when the scans start and end (Zacharias et al., 2013:951). Thus, when developing DRL values, single-phase examinations should be separated from multi-phase ones (Tsapaki, Damilakis, Paulo, Schegerer, Repussard, Jaschke & Frija, 2021:4462). When DRL values are established for multi-phase CT examinations, the average $CTDI_{vol}$ (Lee, Beveridge, Sanagou & Thomas, 2019:12) should be used, while the total $CTDI_{vol}$ for single-phase CT scans is used to calculate CT DRL values. In this research study, the total $CTDI_{vol}$ was used to calculate the DRL values since all selected CT scans were performed in a single phase.

Most CT scans use ATCM or automated exposure control (AEC); these systems automatically adjust the mAs to increase in parts of the body with greater attenuation

and decrease in parts of the body with lower attenuation (Raman et al., 2013:841). The ATCMs used at the participating hospital are SmartmA and AutomA. Hwang et al. (2021) also reported using ATCM in their study, however, it was not made clear which type of ATCM that was used. When SmartmA and AutomA are both enabled, the system uses the oval ratio of the patient to determine how to distribute the mA around the patient as the CT tube rotates (Bruesewitz, Yu, Vrieze, Kofler & McCollough, 2008:2). By using this technological technique, the mA is reduced along the thinner direction, thus reducing the patient radiation dose (Bruesewitz et al., 2008:2).

Iterative reconstruction (IR) algorithm techniques were developed to reduce the radiation dose to patients while still achieving high image quality (Alsleem, Tajaldeem, Almutairi, Almohiy, Aldaais, Albattat, Alsleem, Adbuelhia, Kheiralla, Alqahtani, Alghamdi, Aljondi & Alharbi, 2022:1747). The IR used in the participating hospital is Adaptive Statistical Iterative Reconstruction (ASIR). Unlike the standard filtered back projection (FBP), ASIR reduces image noise and ionising radiation during CT scans without compromising image quality (Chen, Jin, He & Zhao, 2014:1). Both the ATCM and IR were proved to reduce radiation dose by the ICRP (2017:18, 32).

The ICRP (2017:97) also recommends that the DRL values should be based on the patient size since they are considered to be more accurate and should be used when the patient's size is available. This is because, in CT, the patient size plays an important role in determining the amount of radiation required to achieve appropriate image quality for a given procedure (ICRP, 2017:80). Therefore, the LDRL values developed in this study are also based on the dose quantity SSDE, which incorporates the patient size as stated by AAPM (2011:18).

The ICRP (2017:33) advises that DRL values be established based on the clinical indication, for it is of little value to set DRL values without the clinical indication. This is because various clinical indications of the same anatomical structure may require different exposures or examinations/protocols (ICRP, 2017:32). In this study, LDRL values were developed for nephroblastoma, and the researcher reported on the CTDI_{vol}, DLP and SSDE for age groups, weight groups and effective diameter groups of paediatric patients. To the best of the researcher's knowledge, only Almén, Guðjónsdóttir, Heimland, Højgaard, Waltenburg and Widmark (2022) developed

paediatric DRL values for CT abdomen, based on the clinical indications using weight and age for grouping of patients. Almén et al. (2022:5) denoted the clinical indication as tumour and infection; however, the type of tumour and infection was not specified. In contrast to our study, Almén et al. (2022) did not list age groups or use SSDE. Table 2.3 summarises the paediatric DRL values for CT abdomen based on the clinical indication.

Table 2.3. Clinical-indicated DRL values for paediatric CT abdomen examination.

Study	Clinical Indication	Weight groups	CTDI _{vol} (mGy) (75 th percentile)	DLP (mGy cm) (75 th percentile)
Almén et al. (2022)	Tumour and infection	15 - <30 kg	3	61
		30 - <50 kg	4	87
		50 - <70 kg	3	80

CTDI_{vol} = volume computed tomography dose index, DRL = diagnostic reference levels, DLP = dose length product, kg = kilogram, mGy = milligray, mGy.cm = milligray per centimetre.

Age was used as an additional grouping factor for the aim of comparing weight-based DRL values with age-based DRL values (Almén et al., 2022:2). Only weight-based DRL values were made available by Almén et al. (2022) due to the following reasons: (i) the European guidelines suggest that weight should be the first choice criteria for categorising when developing DRL values (Almén et al., 2022:2); (ii) 25% of children did not fit into the suggested weight group for their age, and (iii) weight-based DRL values and age-based DRL values differed by 55%. Almén et al. (2022) did not develop paediatric DRL values for effective diameter groups. Effective diameter is considered the most desirable method of categorising paediatric patients when developing DRL values. Therefore, it has been suggested by the ICRP (2017:97) that the effective diameter should be considered as an alternative to weight or an additional method when developing DRL values.

The DRL values developed in the Almén et al. (2022) study are based on the 75th percentile for the CTDI_{vol} and the DLP. The CTDI_{vol} and DLP are indices to the

standardised phantoms and do not account for patient size (ICRP, 2017:116). The use of the SSDE is recommended by AAPM (2011) since it provides more accurate paediatric DRL values than using the $CTDI_{vol}$ and the DLP (ICRP, 2017:116). In this study, patient weight was linked with age development of paediatric LDRL values based on the SSDE and nephroblastoma for contrast-enhanced abdominal CT examinations at the participating hospital. The effective diameter categorising method was also used in this study to compile LDRL values.

2.2.7 Paediatrics diagnostic reference levels on computed tomography abdominal examination

A literature search was conducted to find studies in which paediatric DRL values were developed for CT abdomen examinations. Studies have found that paediatric DRL values were developed for CT abdomen, CT chest, and CT brain/head. In all these studies, only Imai et al. (2015) developed paediatric DRL values specifically for CT abdomen. Muhammad et al. (2020), Van der Merwe and Mahomed (2020), Hwang et al. (2021) and Satharasinghe et al. (2022) developed paediatric DRL values for CT brain/head, CT chest, and CT abdomen. Table 2.4 summarises and focuses only on the paediatric DRL values developed for CT abdomen in these studies.

**Table 2.4.** Paediatric Diagnostic Reference Levels median and 75th percentile developed for CT abdomen by various authors.

Research study	Clinical indication	NDRLs/ RDRLs/ LDRLs/ Typical DRLs	Weight groups (kg)	Age groups (months/ years)	Effective diameter groups (cm)	(75 th percentile) and/or median					
						CTDI _{vol} (mGy)	DLP (mGy.cm)	SSDE _{AP} Dimension (mGy)	SSDE _{LAT} Dimension (mGy)	SSDE Effective Diameter (mGy)	SSDE _{SUM} Dimension (mGy)
						(75 th percentile) median	(75 th percentile) median	(75 th percentile) median	(75 th percentile) median	(75 th percentile) median	(75 th percentile) median
Imai et al. (2015) [#]	N/I	LDRLs	-	1 year	-	(3.5)	(133.6)	-	-	-	(3.6)
			-	5 years	-	(1.9)	(97.4)	-	-	-	(4.2)
			-	10 years	-	(2.9)	167.0	-	-	-	(5.4)
			-	<15 years	-	(9.0)	(680.8)	-	-	-	(14.4)
Bibbo et al. (2016)	N/I	NDRLs	0–7 kg (n = 13)	-	-	(4.0)	(126)	-	-	-	-
			>7–11 kg (n = N/A)	-	-	-	-	-	-	-	-
			>11–22 kg (n = 88)	-	-	(2.0)	(91)	-	-	-	-
			>22–40 kg (n = 79)	-	-	(4.0)	(221)	-	-	-	-
			>40–55 kg (n = 58)	-	-	(7.0)	(459)	-	-	-	-
			>55–80 kg (n = 36)	-	-	(7.0)	(461)	-	-	-	-
			80 kg (n = 13)	-	-	(12.0)	(828)	-	-	-	-
			-	<5 years (n = 33)	-	(2.4)	(74.0)	-	-	-	-
			-	5–10 years (n = 73)	-	(4.7)	(168.0)	-	-	-	-



			-	>10 years (n = 241)		(7.0)	(365.0)	-	-	-	-
European Commission (2018)	N/I	LDRLs	<5 kg (n = N/A)	-	-	-	(45)	-	-	-	-
			5 - <15 kg (n = N/A)	-	-	(3.5)	(120.0)	-	-	-	-
			15 - <30 kg (n = N/A)	-	-	(5.4)	(150.0)	-	-	-	-
			30 - <50 kg (n = N/A)	-	-	(7.3)	(210)	-	-	-	-
			50 - <80 kg (n = N/A)	-	-	(13)	(480)	-	-	-	-
Muhammad et al. (2020)	N/I	LDRLs	-	(0 - <1Y) (n = 7)		(3.0) 3.0	(116.0) 98.1	-	-	-	-
			-	(1Y - <5Y) (n = 95)		(6.0) 4.6	204.0 (150.2)	-	-	-	-
			-	(5Y - <10Y) (n = 94)		(11.0) 7.1	(419.0) 292.6	-	-	-	-
			-	(10Y - <15Y) (n = 110)		(16.0) 11.7	(911.0) 644.9	-	-	-	-
Hwang et al. (2021)*	N/I	LDRLs	<5 kg (n = 110)	1M (n = 17)		(1.4) 1.4	(30.0) 24.1	-	-	-	(3.7) 3.5
			5 - <15 kg (n = N/A)	1M - <4Y (n = 259)		(2.2) 1.9	(73.8) 59.9	-	-	-	(4.8) 4.1
			15 - <30 kg (n = N/A)	4Y - <10Y (n = 520)		(2.7) 2.3	(101.2) 94.1	-	-	-	(5.5) 4.2
			30 - <50 kg (n = N/A)	10Y - <14Y (n = 496)		(4.0) 2.6	(168.8) 121.1	-	-	-	(6.6) 4.4
			50 - <80 kg (n = N/A)	14Y - <18Y (n = 333)		(4.7) 3.7	(233.0) 179.8	-	-	-	(7.3) 5.6
				-	< 13 cm (n = 61)	1.4 (1.8)	32.0 (46.2)	-	-	-	3.5 (4.1)
				-	14–16 cm (n = 7)	1.9 (2.3)	66.5 (79.0)	-	-	-	4.0 (5.0)
				-	17–20 cm (n = 7)	2.2 (3.0)	107.6 (112.6)	-	-	-	4.1 (5.7)
				-	21–24 cm (n = 7)	2.9 (4.3)	153.9 (190.5)	-	-	-	4.8 (7.1)



				-	>24 cm (n = 7)	3.9 (5.0)	201.4 (238.2)	-	-	-	6.0 (7.2)
Almén et al. (2022)	Tumour and infection	RDRLs	15 - <30 kg (n = 60)	-	-	(2.6)	(91.7)	-	-	-	-
			30 - <50 kg (n = 82)	-	-	(3.4)	(150)	-	-	-	-
			50 - <70 kg (n = 57)	-	-	(5.0)	(247)	-	-	-	-
Satharasinghe et al. (2022)	N/I	NDRLs	-	(0 - 1Y) (n = 47)	-	(4.5) 3.8	(143.5) 103	-	-	(11.0) 9.1	-
			-	(1Y - <5Y) (n = 43)	-	(6.1) 4.1	(142.0) 103	-	-	(13.5) 9.1	-
			-	(5Y - <10Y) (n = 51)	-	(10.3) 6.5	(247.0) 221	-	-	(19.6) 13.6	-
			-	(10Y - <15Y) (n = 69)	-	(11.9) 10.3	(603.0) 436	-	-	(22.1) 19.5	-
			-	-	0–14.5 cm	4.1 (5.2)	115 (142)	-	-	9.1 (12.6)	-
			-	-	14.5–18.0 cm	8.9 (11.3)	247 (436)	-	-	17.2 (21.9)	-
			-	-	18.0–22.0 cm	10.3 (10.6)	436 (436)	-	-	18.8 (19.6)	-
			-	-	22.0–25.0 cm	16.1 (17.6)	605 (606)	-	-	25.2 (26.7)	-

AP = anterior-posterior, cm = centimetre, CTDI_{vol} = volume computed tomography dose index, DLP = dose length product, kg = kilogram, LAT = lateral, LDRLs = local diagnostic reference levels, mGy = milligray, mGy.cm = milligray per centimetre, M = month, N/A = not available, NDRLs = national diagnostic reference levels, N/I = not indicated, RDRLs = regional diagnostic reference levels, SSDE = size-specific dose estimate, Y = years, Hwang et al. (2021) did not have DRL values for age and weight separately. The specific SSDE parameter for the study conducted by Hwang et al. (2021) was not indicated. #The specific SSDE parameter for the study conducted by Imai et al. (2015) was not indicated.

2.2.8 Benefits of calculating clinical DRL values for paediatric patients

Most of the existing DRL values have been developed based on anatomical locations (Paulo, Damilakis, Tsapaki, Schegerer, Repussard, Jaschke, Frija & European Society of Radiology, 2020:9). However, this approach had some limitations when used for various CT examinations. In some cases, CT examinations performed at the same anatomical location may be performed for different clinical indications, resulting in different protocols and exposure levels (Zira, Yahaya, Umar, Nkubli, Chukwuemeka, Sidi, Emmanuel, Ibrahim, Laushugno & Ogenyi, 2020:2). For example, if a CT scan is performed on the abdomen to exclude renal calculi, the DRL quantity will be lower than if a CT scan is performed on the abdomen to diagnose a tumour (ICRP, 2017:32). Paulo et al. (2020:8) concluded that continued development of DRL values without considering the clinical indication would not adequately fulfil the main purpose of the DRL, which is to assist in optimising radiation exposure. The ICRP (2017:33) also stated that setting a DRL without considering clinical indication is of little meaning. Therefore, this study was performed to develop paediatric LDRL values based on the most common clinical indications for contrast-enhanced abdominal CT examinations at the participating hospital.

2.3 CONCLUSION

Previous studies referenced in this literature review have proved that CT scans deliver an expressively higher radiation dose than general radiography and fluoroscopy. The use of CT in paediatric patients raises concern since children's organs and tissues are inherently more prone to cellular damage, which increases the risk of cancer over a child's lifetime (Almohiy, 2014:1). Computed tomography paediatric examinations must be justified and optimised to avoid unnecessary radiation doses. A main component of optimisation is the development of DRL values (Saravanakumar et al., 2016:342). This chapter outlined various factors contributing to establishing paediatric LDRL values for contrast-enhanced abdominal CT examinations based on nephroblastoma, using the SSDE as a dose quantity, wherein the age is linked to the weight for categorising.



Chapter 3, entitled **Methodology**, outlines the methodology of this study. The methodology of the study describes the data collection process, analysis, and how the data were protected.

CHAPTER 3: METHODOLOGY

3.1 INTRODUCTION

Computed tomography (CT) scans have severe deterministic and stochastic effects due to previous sub-optimal scanning protocols. As a result, it is therefore important to justify and optimise paediatric CT examinations (Järvinen et al., 2015:87). Through careful optimisation, CT scans can be conducted with minimal risk to children. The development of DRL values is considered to be the effective basis of optimisation (Saravanakumar et al., 2016:342). Chapter 2 discussed the CT dose quantities ($CTDI_{vol}$, DLP and SSDE) used to calculate DRL values. Furthermore, various considerations and how these elements contribute to establishing paediatric LDRL values were also discussed.

The aim of the study was to establish paediatric LDRL values for contrast-enhanced abdominal CT examinations to investigate and stage nephroblastoma cases. This chapter discusses the methods that were used to develop paediatric LDRL values in this study.

3.2 RESEARCH DESIGN, MATERIALS AND METHODS

The methods describe how the study was designed, what tool was used to collect the data, and how the data were analysed.

3.2.1 Research approach

A quantitative research approach was used for this study. Quantitative research involves systematically investigating social phenomena through statistical or numerical data (Watson, 2015:44). For this research study, the researcher established paediatric LDRL values for contrast-enhanced abdominal CT examinations by obtaining numerical data for each patient who was analysed statistically.

3.2.2 Research design

The study followed a descriptive research design, and data collected from 1 January 2018 to 31 December 2021 from paediatric patients who underwent CT abdominal examination to diagnose nephroblastoma were collected retrospectively. The purpose of this descriptive research design was to investigate variables such as patient age, patient diameter in centimetres (cm), patient weight in kilogram (kg), total CTDI_{vol}, DLP, SSDE_{AP} dimension, SSDE_{LAT} dimension, SSDE_{Effective} diameter and the SSDE_{SUM} dimension to compile DRL values. Unlike experimental research, variables were not controlled; they were only observed and measured (McCombes, 2019: online).

3.2.3 Research tool

In this research study, the researcher used a structured data recording document (Appendix A) to descriptively gather dose information from the dose reports on the picture archiving and communication system (PACS) or CT console. The structured data recording document was obtained from Public Health England (2014) in the study titled “Doses from computed tomography (CT) examination in the UK – 2011 Review”, which was adjusted according to this research study. The structured data recoding document from Public Health England (2014) well aligned with this study as it contained elements needed to develop DRL values for this study. The elements in the structured data recording document that were adopted from the Public Health England (2014) include: name of machine; number of detector rows; age; gender; iodinated contrast used; CT examination; CT protocol; CTDI_{vol}; DLP; AP dimension and LAT dimension. The structured data recording document was adjusted by adding other elements that were needed for this study, such as the clinical indication, effective diameter, weight derived, machine model, and the sum of the AP and LAT diameter dimensions.

According to the ICRP (2017:39), the primary variables that should be recorded are those that can be readily assessed, preferably from direct measurements taken during the examination. Therefore, the structured data recording document contained primary information necessary for developing proposed LDRL values, such as the patient's age, weight, the clinical indication (nephroblastoma) for the examination, AP

dimension, LAT dimension, effective diameter, $CTDI_{vol}$ and the DLP. This information was used to develop paediatric LDRL values for contrast-enhanced abdominal CT examinations. The patients' ages and weights were collected to categorise the patients into groups specified in section 3.2.6. The AP dimension, LAT dimension and effective diameter were collected to calculate the SSDE needed for this study.

3.2.4 Pilot study

The pilot study was conducted on the 21st of September 2021 to test this research approach's feasibility before executing the study at the participating hospital in Bloemfontein, Free State Province, in South Africa. The aim of the pilot study was to test the structured data recording document, sampling techniques and the accessibility of information required to develop proposed LDRL values. Five paediatric contrast-enhanced abdominal CT examinations that adhered to the inclusion criteria and dose reports were pilot-tested to determine if the research tool was valid, reliable, and trustworthy. The structured data recording document, adapted from Public Health England (2014),) was found to be feasible, and no changes were made to the research tool. Thus, the data from the pilot study formed part of the sample size for the main study.

3.2.5 Target population

The target population of this study consisted of paediatric patients who presented with nephroblastoma for contrast-enhanced abdominal CT examinations at the participating hospital between 1 January 2018 and 31 December 2021. Out of 265 patients that were collected from 1 January 2018 to 31 December 2021 that formed part of the study population, only 120 patients adhered to the inclusion criteria of this study to form sample size. The study population had to adhere to the inclusion criteria to form part of the research study. Initially, it was planned to retrieve data from January 2016, but the CT department no longer had the patient register file for 2016 and 2017; thus, data were retrieved from 1 January 2018 to 31 December 2021.

3.2.6 Sample strategy and size

The sampling techniques used to collect data for this study were stratified and purposive. Taherdoost (2016:23) defines purposive sampling as an approach in which specific participants or events are selected purposely to provide significant information that cannot be attained from other choices. A purposive sampling approach was used when patients were selected, types of examinations, and clinical indications for which LDRL values needed to be determined. For this study, a purposive sampling fitted to answer the research question with the data collected to develop paediatric LDRL values. Stratified sampling divides the population into subgroups, and a sample is collected from each subgroup. In this study a stratified sampling to randomly select paediatric patients based on age and weight, as seen in Figure 3.1 (Taherdoost, 2016:21) was used.

The patients were categorised into five age groups and five weight categories, as the ICRP (2017:93) suggested. The age and weight categories are illustrated in Figure 3.1. The grouping of patients according to their *age* was as follows: age group 1 [<1 month (M)); age group 2 [1M to <4 years (Y)); age group 3 [4Y to <10Y); age group 4 [10Y to <14Y), and age group 5 [14Y to <18Y). The *weight* was used to group the patients as follows: weight group 1 [0kg - <5kg), weight group 2 [5kg - <15kg), weight group 3 [15kg - <30kg), weight group 4 [30kg - <50kg) and weight group 5 [50 kg to <80 kg). The paediatric patients were also grouped into *effective diameter* groups (see Figure 3.2) as follows: effective diameter group 1 [<13 cm); effective diameter group 2 [13 cm to <16 cm); effective diameter group 3 [16 cm to <20 cm); effective diameter group 4 [20 cm to <24 cm), and effective diameter group 5 [>24 cm).

The ICRP (2017:82) states that 20 to 30 patients are required per group to establish DRL values when the data are collected using a paper form. Thus, a minimum of 20 patients for each age and weight category were included in this study. During data collection process, only 120 paediatric patients met the inclusion criteria of this study for the study period. The sample size of the paediatric patients who formed part of this research study was 120 patients for contrast-enhanced abdominal CT examination ($n_{patients} = 120$).

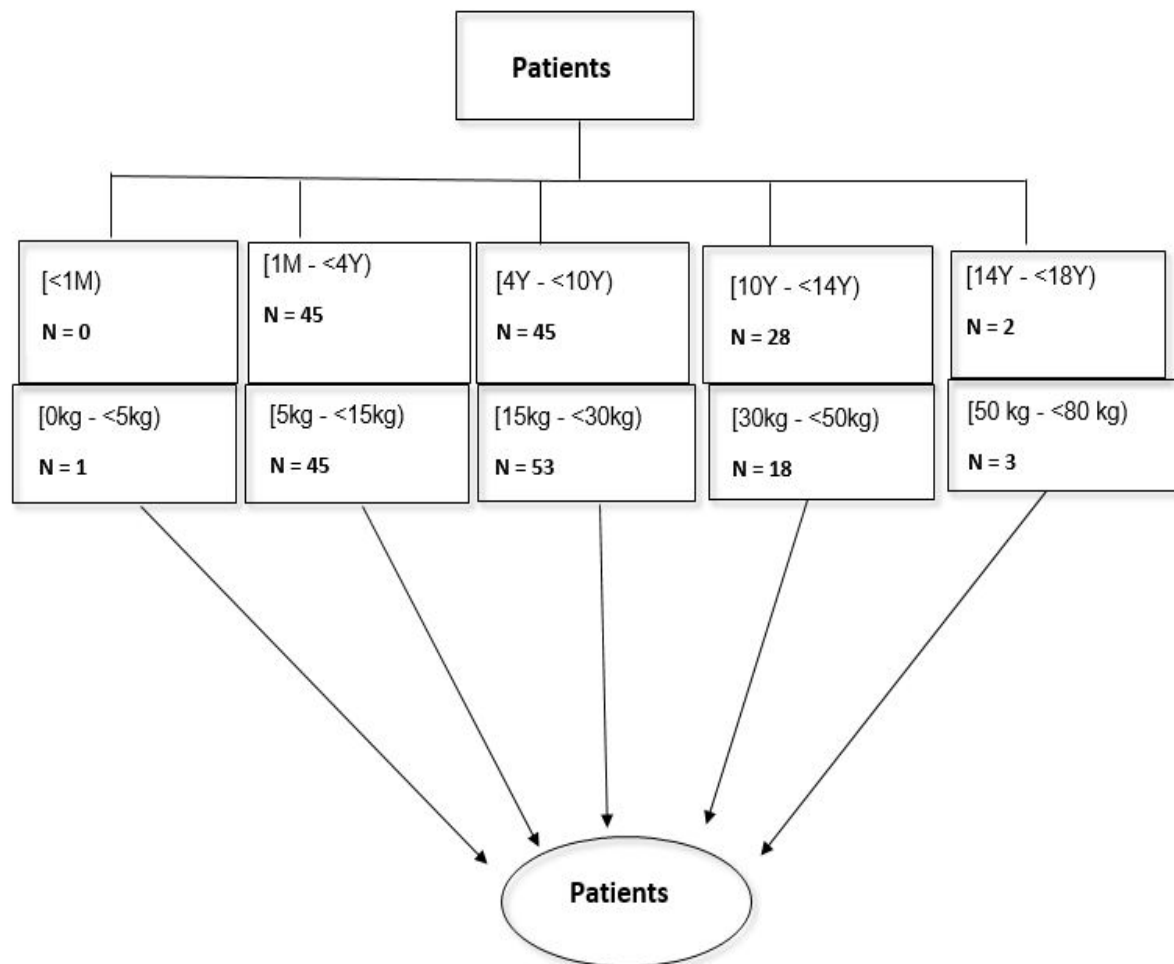


Figure 3.1. Illustration of the stratified sampling technique used for this study to select the participants for each category (age and weight).

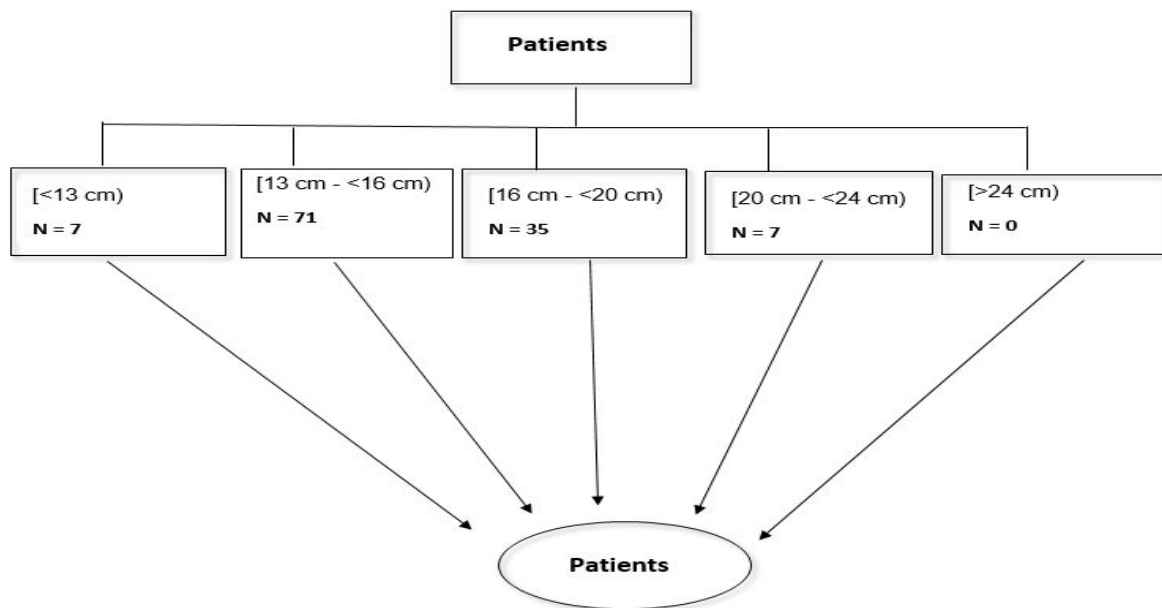


Figure 3.2. Illustration of the grouping for effective diameter.

3.2.7 Inclusion and exclusion criteria

The sample of patients had to adhere to the inclusion criteria to form part of the study.

The inclusion criteria for this study were as follows:

- Patients aged 0 to 17 years who weighed between 0 and 80 kg were considered paediatric patients and included in the study (EC, 2018:35, 110).
- Only the patients who presented with nephroblastoma and who underwent contrast-enhanced abdominal/chest-abdomen CT examinations from 1 January 2018 until 31 December 2021 were included in this study.

The patients who did not adhere to the inclusion criteria of the study were excluded.

The exclusion criteria for this study involved:

- Patients who were 18 years and older were excluded from the research study since these patients were regarded as adults (EC, 2018:35, 110).
- Patients who did not present with nephroblastoma for contrast-enhanced abdominal CT examinations from the 1st of January 2018 until the 31st of December 2021 were excluded.
- Patients booked for CT examinations of the brain-chest-abdomen, neck-chest-abdomen, neck-chest-abdomen-pelvis, pulmonary angiogram and/or abdominal angiogram were also excluded from the research study.

3.3 DATA GATHERING

The data-gathering process commenced once ethical approval had been obtained from the Health Sciences Research Ethics Committee (HSREC) at the University of the Free State to conduct this study. The researcher visited the imaging department at the participating hospital from 8 to 12 October 2022 and also on 24 December 2022 to complete the data collection. Patient data were retrieved from 1 January 2018 to 31 December 2021 from the PACS until the sample of 120 paediatric patients from the imaging department was gathered for contrast-enhanced abdominal CT examinations. Visits to the department began on the weekend of 8 October 2022 and ended after hours on 12 October 2022. The data were collected over the weekend and after hours to ensure that the workflow of the imaging department was not compromised. Only the researcher was directly involved in the data-gathering process. A structured data recording document (Appendix A) was used during this data-gathering period to obtain the CTDI_{vol}, DLP, clinical indication, AP dimensions, LAT dimensions, effective diameter, age, and weight of the patients.

First, the patient register file in the CT department was scanned visually to find patients aged between 0 and 18 years who had undergone a contrast-enhanced CT abdomen examination. The patients found on the patient register file were documented on a separate sheet with their examination number, date of the examination, and volume of contrast injected. The patients were categorised according to specified age groups. In the event that the weight of the patient was not recorded, the volume of contrast media was used to calculate the patient's weight. The weight was required to exclude patients who weighed more than 80 kg and categorise patients into specified weight groups. The volume of contrast injected is usually calculated by multiplying the patient's weight by 1.5 at the participating hospital (Equation 1). Therefore, patient weight in this study was calculated by inverting the calculation, which is dividing the volume of contrast injected by 1.5 to get the weight of the patient (Equation 2).

$$\text{Weight} \times 1.5 = \text{amount of contrast injected} \quad (\text{Equation 1})$$

$$\text{Weight} = \text{amount of contrast injected} \div 1.5 \quad (\text{Equation 2})$$

Second, the PACS was searched for medical reports, dose reports, and CT images of patients who met the inclusion criteria. Medical reports were used to find patients with nephroblastoma and excluded patients whose clinical history did not refer to suspected/queried/confirmed nephroblastoma. The dose reports were used to record the DLP and $CTDI_{vol}$ on the structured data recording document for every patient.

Third, the CT images were used to measure the AP and LAT dimensions of the patients to determine the sum of the AP and LAT dimensions and the effective diameter in centimetres (cm) to calculate the SSDE. The AP and LAT measurements were made using MicroDicom viewer (mDicom) version 3.2.7 (MicroDicom Ltd; Sofia, Bulgaria). The AP measurements were made at the level of the vertebral bodies between thoracic vertebrae 12 and lumbar vertebrae 3, and the LAT measurements were made at the centre of both kidneys on a CT axial image. Electronic calipers were used to obtain these measurements, and the results were captured on the structured data recording document. Figure 2.5 of Chapter 2 illustrates how the AP and LAT dimensions were measured on an axial CT image. The SSDE was calculated based on the AP dimension, LAT dimension, the sum of the AP and LAT dimensions and the effective diameter.

The information from the patient register file, and the PACS were recorded on the structured data recording document for all the patients who adhered to the inclusion criteria of the study. Following the exact steps mentioned in this study, it took approximately 10 to 20 minutes to search, find and download the information of a single patient from the patient register file and PACS.

3.4 DATA ANALYSIS

The data were captured electronically from the structured data recording document and entered into the Microsoft Excel programme. The age and weight groups were adjusted based on the available data and supported by the ICRP (2017:93). The researcher only provided the statistician with the collected data of patient who adhered to the inclusion criteria. The statistician indicated that this is a big enough sample size to render scientific results. Further analysis was performed by a biostatistician using SAS Version 9.4 software to answer the research question. Descriptive statistics, namely distribution frequencies and percentages, were calculated for categorical data,

means and standard deviations or median and percentiles were calculated for numerical data. The Shapiro-Wilk test was used to investigate if cardinal numerical data followed a normal distribution. The Shapiro-Wilk test was used to determine whether the mean, standard deviation, median and/or interquartile range (IQR) for the dose quantities must be used to develop the DRL values. To assess the relationship between the variables for each age group, weight group and effective diameter group, Spearman's correlation coefficient and p-values were calculated. In addition, Kruskal-Wallis tests were also performed to observe the overall effect of age groups, weight groups and effective diameter groups on all variables (Choi, Lee, Huh and Kang, 2003:1029). Typical DRL values are defined as the median of the distribution of data (ICRP, 2017:26), while LDRL values are defined as the 75th percentile of the data distribution (Van der Merwe & Mahomed, 2020:3). The studies of Vawda (2017) and Kozłowski, van Reenen and Trauernicht (2024) also used the 75th percentile to develop DRL values for one hospital. Therefore, DRL values for this study were based on the 75th percentile for each category.

3.5 VALIDITY AND RELIABILITY OF THE DATA RECORDING DOCUMENT

Reliability and validity refer to assessing and reducing errors associated with measurements, using a given research tool (Watson, 2015:45).

3.5.1 Reliability

The research tool used in this study was a structured data recording document. Watson (2015:45) indicates that the reliability of an instrument is determined by its ability to measure the same value each time. This research study used a structured data recording document designed to consistently produce consistent results. Specific information was required for all the abdominal CT examinations, such as the patient's age, weight, the CTDI_{vol} and the DLP, to establish LDRL values for nephroblastoma. Mathematical equations were used to calculate the SSDE and determine the patient's weight if it was absent in the CT register file. Moreover, a pilot study was conducted to ensure that the structured data recording document was producing consistent results, namely LDRL values. All these aspects contributed towards the reliability of the study.

3.5.2 Validity

Watson (2015:45) defines validity as the degree to which a measurement accurately reflects the researcher's interests. Content validity is a type of validity that assesses whether the content of the research tool covers all relevant parts of the subject it intends to measure (Middleton, 2019: online). The structured data recording document was adopted from Public Health England (2014) (see section 3.2.3) and altered according to this research study to ensure that content validity was measured. In addition, the structured data recording document was pilot-tested before the main study, which showed that the research tool measures the possibility of establishing LDRL values for nephroblastoma for paediatric patients at the participating hospital.

3.6 ETHICAL CONSIDERATIONS

The ethical considerations in this study were adhered to ensure that the study would be safe and secure. Ethical considerations included ethical approval, informed consent, participant withdrawals, project safety, patient safety, financial implications, and privacy rights.

3.6.1 Ethical approval

The proposal for the research study was submitted to the HSREC at the University of the Free State in Bloemfontein to obtain ethical approval. Ethical approval was obtained from HSREC, as seen in Appendix B (UFS-HSD2022/0341/3008-0001). The researcher used patient information from the CT console/PACS at the participating hospital located in Bloemfontein; as a result, permission was obtained from the Free State Department of Health (DoH) (Appendix C). Permission was also obtained from the head of the imaging department at the participating hospital (Appendix D).

3.6.2 Informed consent

This study did not require written informed consent since data capturing was retrospective and anonymised CT dose data were used (Aberle, Ryckx, Treier &

Schindera, 2019:10). Furthermore, the researcher did not make any additional measurements on the patient that did not form part of the routine CT procedure; hence, informed consent was not required from the parent, guardian or referring physician to carry out this study. Many retrospective studies that were conducted to develop DRL values waived informed consent. Some of these studies include “Diagnostic reference level of radiation dose and image quality among paediatric CT examination in a tertiary hospital in Malaysia” (Muhammad et al., 2020) and “Update of national diagnostic levels for adult CT in Switzerland and assessment of radiation dose reduction since 2010” (Aberle et al., 2019:10).

3.6.3 Participant withdrawal

The participating imaging department could withdraw from the study at any time and would not be penalised for withdrawing.

3.6.4 Participant/Patient safety

This study did not require additional examinations that added radiation to the overall patient dose since the study was conducted retrospectively. Patients’ personal information, such as their name and surname, was kept confidential; patients’ information was captured using a unique identification number in this study. The unique identification was formed by combining a group number and numerical order of the patients, e.g. G1P1.

3.6.5 Financial implications

There were no financial implications for the respective imaging department at the participating hospital.

3.6.6 Right of privacy

Patients’ general personal information, namely the age, gender and examination number obtained in this study, was handled strictly professionally and confidentially. In this study, the researcher adhered to the principles of POPIA (protection of Personal Information Act) act by not mentioning the patients’ personal information, such as

names, surnames and identification numbers; hence, a unique number was used and included in the structured data recording document (Appendix A). This was used to capture the patient's general personal information and the data from the PACS, CT computer and CT register. The structured data recording documents were bound together and stored in a secure, private place. The portable computer that was used to store the data on Microsoft Excel was password protected. The hard drive that was used to store downloaded digital imaging and communications in medicine (DICOM) information (CT images and dose reports) from PACS was also password protected using BitLocker encryption of Windows 10 (Microsoft Corporation, Redmond, WA 98052-6399, USA). The analysed data are available only to the researcher, biostatistician and the two supervisors of this study and can only be accessed using passwords. The name of the participating hospital was not disclosed in this study. All the data collected for this study were kept private to maintain the patients' right to privacy, as well as that of the participating hospital.

3.7 CONCLUSION

This chapter detailed methods that were followed to develop paediatric LDRL values for contrast-enhanced abdominal CT examinations based on nephroblastoma and patient size. The CT dose quantities, patient age, and weight of 120 patients were retrospectively collected using a structured data recording document. Patients were divided into age, weight, and effective diameter groups to develop LDRL values for paediatric patients participating in this study. Using the data analysis described in this chapter, paediatric LDRL values were developed based on the 75th percentile.

Chapter 4, entitled ***Results and discussion***, provides the results of the study and discusses the analysed data and reports on the established paediatric LDRL values.

CHAPTER 4: RESULTS AND DISCUSSION

4.1 INTRODUCTION

This chapter provides the conclusions from the analysed data and reports on the paediatric LDRL values established in this study. The aim of this study was to establish paediatric LDRL values for contrast-enhanced abdominal CT examinations to diagnose and/or stage nephroblastoma cases in paediatric patients. The first objective was to establish LDRL values based on the age and weight of the paediatric patients at the participating hospital. The second objective was to compare LDRL values that were calculated using the weight versus those calculated using the effective diameter of the patient. The third objective was to compare the clinical indication-based LDRL values with other internationally published clinical indication-based LDRL values.

4.2 RESULTS OF THE RESEARCH STUDY

The paediatric LDRL values developed in this study were based on the median and the 75th percentile of median data distribution, as presented in Tables 4.3, 4.7 and 4.11. The paediatric LDRL values calculated using the patient's weight were compared with the paediatric LDRL values calculated using the effective diameter, and the results are indicated in Table 4.14. The differences between dose quantities ($CTDI_{vol}$, DLP, $SSDE_{AP}$ Dimension, $SSDE_{Effective\ Diameter}$, $SSDE_{LAT}$ Dimension and $SSDE_{SUM}$ Dimension) and the correlation among the study groups and dose quantities were also determined. In addition, the clinical indication-based LDRL values developed in this study were compared with other internationally published clinical indication-based LDRL values, as indicated in Table 4.18.

4.2.1 Computed tomography unit

The contrast-enhanced abdominal examinations of paediatric patients that formed part of this study were performed with the General Electric (GE) Healthcare CT unit. The unit specifications are shown in Table 4.1. The annual quality control (QC) tests were performed on the CT unit (see Table 4.1). The results of the QC test adhered to the

recommended guidelines, as discussed in Chapter 2 of this study. Thus, the paediatric LDRL values presented in this study are deemed reliable.

Table 4.1. Computed tomography unit specifications and quality control test dates.

CT UNIT						
Make	Model	Serial No.	Date of installation	Date of upgrade	ATCM	IR algorithm
GE Healthcare	Discovery CT750HD	420829CN4	15/11/2010	23/07/2018	Smart mA & Automatic mA	ASIR & FBP
ANNUAL QUALITY CONTROL TEST DATES						
Dates of inspection	23/10/2018	22/10/2019	21/10/2020	21/10/2021	28/10/2022	
Dates of report	25/10/2018	24/10/2019	26/10/2020	25/10/2021	30/10/2022	

ATCM = automatic tube current modulation, mA = milliamperes, IR = iterative reconstruction, ASIR = adaptive statistical iterative reconstruction, FBP = filtered back projection.

4.2.2 Computed tomography examination

The target population of this study comprised paediatric patients who presented with nephroblastoma or were suspected of having nephroblastoma for a contrast-enhanced abdominal CT examination at the participating hospital. All participants underwent a contrast-enhanced CT abdomen-pelvis protocol performed in the portal venous phase from 1 January 2018 until 31 December 2021. The CT abdomen-pelvis examinations were performed with a thin slice thickness, ranging between 0.63 and 2.5 mm and a pitch ranging between 0.53 and 0.97. The dose report indicating the CT dose quantities (CTDI_{vol} and DLP), as well as the radiology reports, were retrieved retrospectively from the PACS. A radiologist employed at the participating imaging department reported all the CT examinations that formed part of this study. According to the dose reports, only one scan phase was performed for all patients who participated in this research study.

4.2.3 Demographics of sample size

The data of 120 patients who adhered to the study's inclusion criteria were analysed. Of the 120 patients, 70 (58%) were male, and 50 (42%) were female. The patients were categorised into five age groups, five weight groups, and five effective diameter groups, as seen in Figures 4.1, 4.2 and 4.3.

The ICRP recommends collecting data of at least 20 to 30 patients per category with agreed weights or ages for CT examinations when developing paediatric LDRL values (ICRP, 2017:50). The effective diameters groups in this study were approximated from the study of Hwang et al. (2021:1174). For easy comparison with weight as per the study objective, 20 to 30 patients per category with effective diameter were required. This was also briefly discussed in Chapter 2 (see section 2.2.5). The data from the age, weight or effective diameter groups with fewer than 20 patients to establish LDRL values for nephroblastoma were excluded. Therefore, LDRL values were established only for

- two weight groups: weight group 2 [5kg - < 15kg), weight group 3 [15kg - < 30kg),
- three age groups: age group 2 [1M to <4Y), age group 3 [4Y to <10Y) and age group 4 [10y to <14y), and
- two effective diameter groups: effective diameter group 2 [13 cm to <16 cm) and effective diameter group 3 [16 cm to <20 cm).

The LDRL values based on the patient's age, weight, and effective diameter are outlined, respectively.

As discussed in section 3.4, Descriptive statistics, namely frequencies and percentages, were calculated for categorical data. Means and standard deviations or medians and percentiles were calculated for numerical data. The Shapiro-Wilk test was used to investigate if numerical data followed a normal distribution. A Spearman's correlation test was used to calculate Spearman's coefficient and p-values to assess the relationship between the dose quantities for each weight group. In addition, Kruskal-Wallis tests were performed to observe the overall effect of the weight groups on all dose quantities (CTDI_{vol}, DLP, SSDE_{AP Dimension}, SSDE_{Effective Diameter}, SSDE_{LAT}

Dimension and SSDE_{SUM} Dimension) and if any significant differences occurred. A p-value of less than 0.05 indicated a significant difference between the proportions in weight groups.

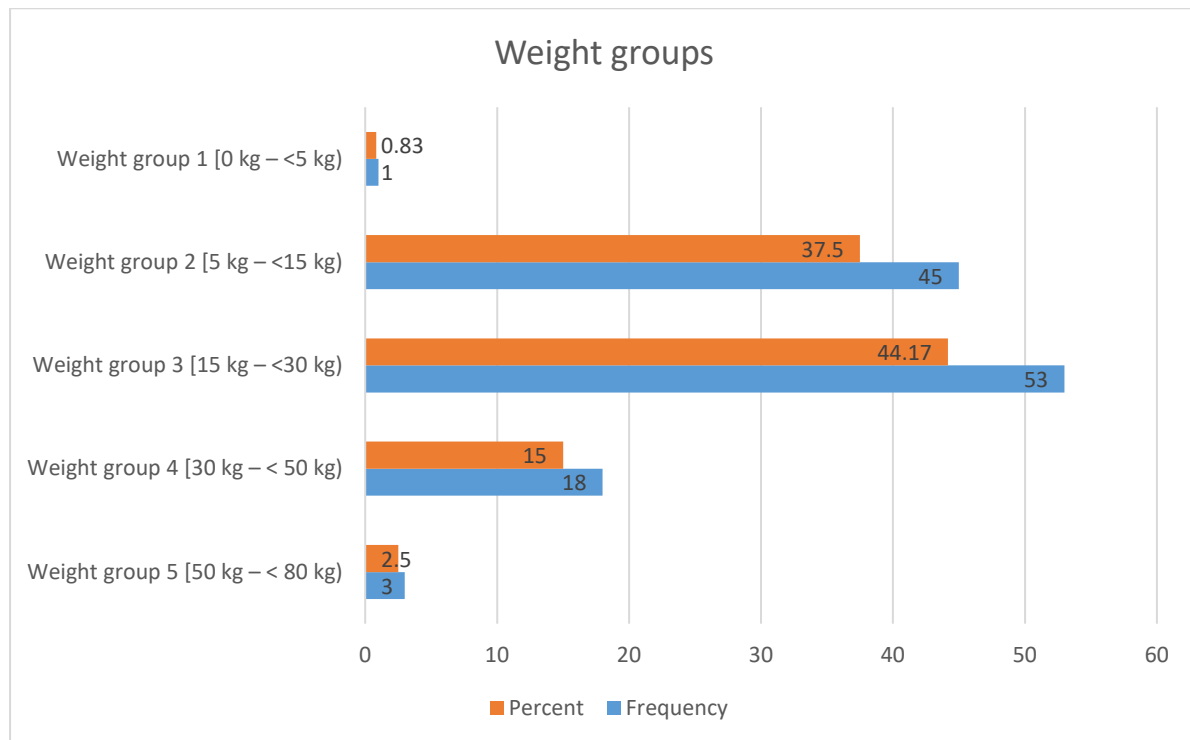


Figure 4.1. Weight group categories and frequency of patients (n = 120).

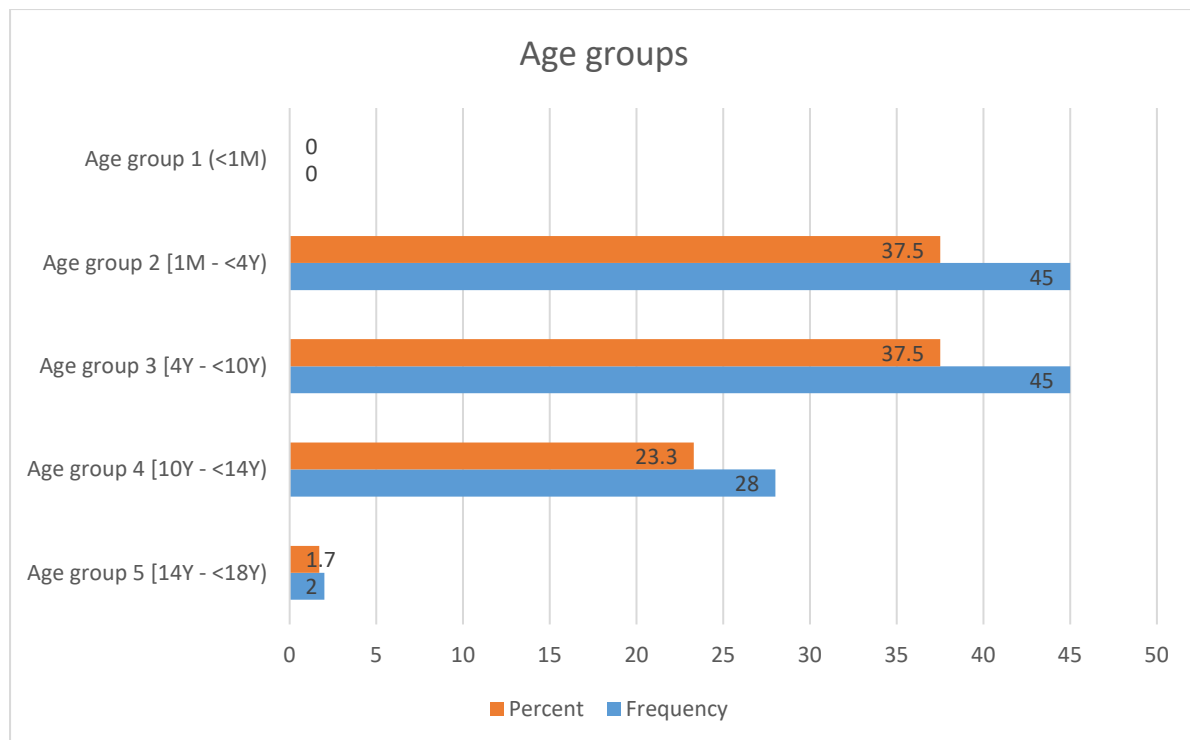


Figure 4.2. Age group categories and frequency of patients (n = 120).

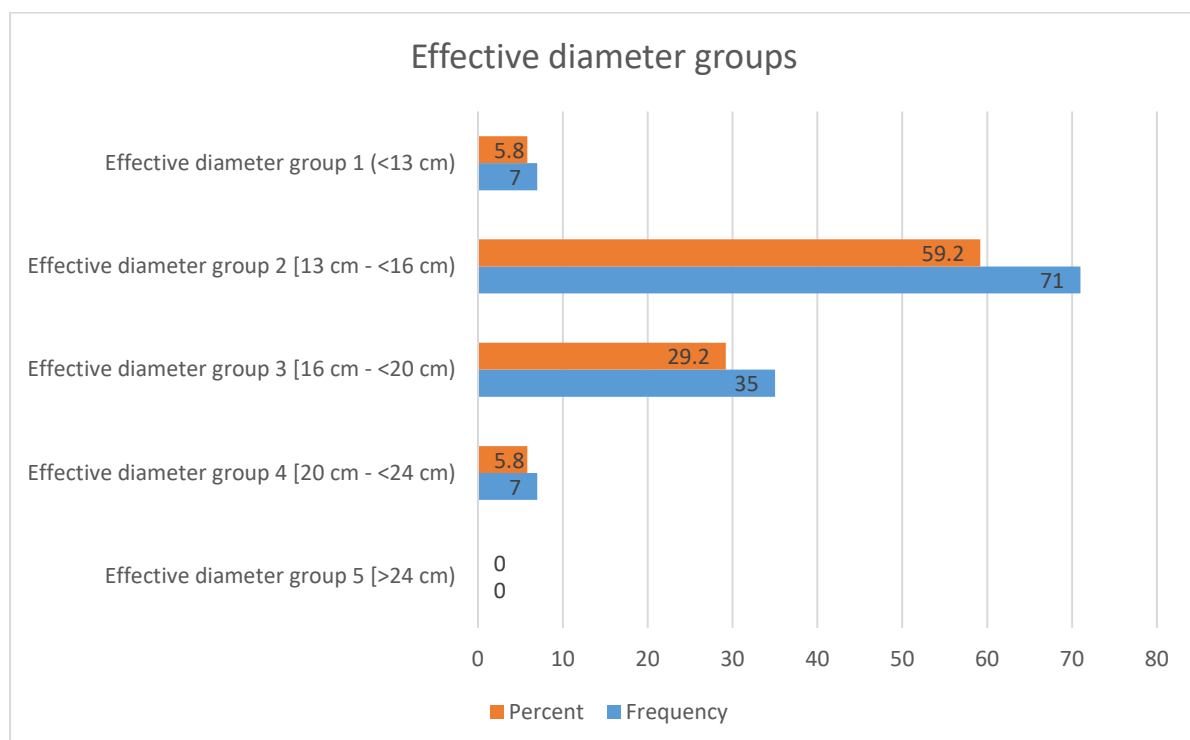


Figure 4.3. Effective diameter group categories and frequency of patients (n = 120).

4.2.4 Diagnostic reference levels according to patient age

In this study, age-based paediatric LDRL values were developed for contrast-enhanced abdominal CT examination based on the clinical indication of nephroblastoma. The Shapiro-Wilk test was first performed to investigate the distribution of the data for the three age groups. The results of the Shapiro-Wilk test were used to conclude whether the mean, standard deviation, median and/or interquartile range (IQR) for the dose quantities should be used to report on the DRL values. If the p-value of the Shapiro-Wilk test for a specific age group was less than 0.05, then the mean and standard deviation of the specific dose quantity should be used to report the DRL value. If the p-value between variables is ≥ 0.05 , then the median and the IQR can be used to report the DRL value. The results of the Shapiro-Wilk test performed on the dose quantities variables ($CTDI_{vol}$, DLP, $SSDE_{AP}$ Dimension, $SSDE_{LAT}$ Dimension, $SSDE_{SUM}$ Dimension and $SSDE_{Effective-Diameter}$) are presented in Table 4.2. The Spearman's correlation coefficient test was calculated to study the relationship between the variables for different age groups.

Table 4.2. Shapiro-Wilk test results performed on the dose quantity variables for the age groups.

Variables	Age groups		
	Group 2 [1M - <4Y) (n = 45)	Group 3 [4Y - <10Y) (n = 45)	Group 4 [10Y - <14Y) (n = 28)
	p-value	p-value	p-value
$CTDI_{vol}$ (mGy)	0.0019 (S)	<0.0001 (S)	0.2658 (NS)
DLP (mGy.cm)	0.5711 (NS)	0.0009 (S)	0.7616 (NS)
$SSDE_{AP}$ Dimension (mGy)	<0.0001 (S)	<0.0001 (S)	0.2206 (NS)
$SSDE_{LAT}$ Dimension (mGy)	<0.0001 (S)	<0.0001 (S)	0.7375 (NS)
$SSDE_{SUM}$ Dimension (mGy)	<0.0001 (S)	<0.0001 (S)	0.1338 (NS)
$SSDE_{Effective-Diameter}$ (mGy)	<0.0001 (S)	<0.0001 (S)	0.0859 (NS)

AP = anterior-posterior, $CTDI_{vol}$ = volume computed tomography dose index, DLP = dose length product, LAT = lateral, mGy = milligray, mGy.cm = milligray per centimetre, M = month, NS = not significant, n = number, S = significant, SSDE = size-specific dose estimate, Y = year.

According to the Shapiro-Wilk tests for normality, the distribution of the age of the participants in age groups 2 and 3 had significant differences except for DLP for age

group 2. Therefore, the median and the IQR were used to report on the $CTDI_{vol}$, DLP and all four size-related SSDE dose parameters (AP dimension, LAT dimension, effective diameter and sum dimension) for age groups 2 and 3. For age group 4, all the variables, as seen in Table 4.2, followed a normal distribution; thus, no significant differences were noted. As a result, the mean and standard deviation are reported for all variables for age group 4.

The EC (2018:14) and the ICRP (2017:45) recommend that LDRL values be set at the 75th percentile of the median data distribution. The ICRP (2017:45) further stated that typical values may be derived from the median of the distribution, if an institution lacks sufficient data to use the third quartile. Therefore, the IQR was reported as the median and 75th percentile for the dose quantities: $CTDI_{vol}$, DLP, $SSDE_{AP}$ Dimension, $SSDE_{LAT}$ Dimension, $SSDE_{SUM}$ Dimension, and $SSDE_{Effective}$ Diameter and to calculate the LDRL values as seen in Table 4.3. The SSDE parameters were calculated by multiplying the total $CTDI_{vol}$ with the conversion factor designated for each variable based on the 32 cm phantom; this method was briefly explained in Chapter 2 (see section 2.2.5.2.1).

Table 4.3. LDRL values based on the 75th percentile and the median for the $CTDI_{vol}$, DLP, $SSDE_{AP}$ Dimension, $SSDE_{LAT}$ Dimension, $SSDE_{SUM}$ Dimension and $SSDE_{Effective}$ Diameter for age groups.

Dose quantities	Age groups			
	Group 2 [1M - <4Y] (n = 45)	Group 3 [4Y - <10Y] (n = 45)	Group 4 [10Y - <14Y] (n = 28)	p-value (Kruskal-Wallis test)
	(75 th percentile) median	(75 th percentile) median	(75 th percentile) median	
$CTDI_{vol}$ (mGy)	(2.7) 2.4	(3.1) 2.6	(7.1) 5.8	<0.0001 (S)
DLP (mGy.cm)	(98.7) 81.4	(131.9) 112.8	(367.9) 262.5	<0.0001 (S)
$SSDE_{AP}$ Dimension (mGy)	(5.6) 5.1	(6.3) 5.4	(12.5) 10.3	<0.0001 (S)
$SSDE_{LAT}$ Dimension (mGy)	(5.8) 5.1	(6.6) 5.4	(12.7) 10.9	<0.0001 (S)
	(5.8)	(6.4)	(12.7)	<0.0001 (S)

SSDE_{SUM} Dimension (mGy)	5.1	5.5	10.8	
SSDE_{Effective Diameter} (mGy)	(5.8) 5.2	(6.4) 5.5	(12.8) 11.1	<0.0001 (S)

AP = anterior-posterior, CTDI_{vol} = volume computed tomography dose index, DLP = dose length product, LAT = lateral, mGy = milligray, mGy.cm = milligray per centimetre, M = month, NS = not significant, n = number S = significant, SSDE = size-specific dose estimate, Y = year.

A Kruskal-Wallis test was also performed based on the median of the dose quantities to determine if the age group of the patients influenced the dose quantities. The p-value results from the Kruskal-Wallis test indicated a significant difference between the patient age groups.

4.2.4.1 Correlation analyses of dose quantities based on patient age

Spearman's correlation coefficient (r) and p-value were calculated to observe the relationship between the dose quantities and age groups. Table 4.4 presents the correlation coefficient and p-value for the dose quantity variables for the age groups. A weak positive correlation, which was non-significant, was observed between dose quantities (CTDI_{vol} and DLP) and age for all age groups. All the SSDE parameters had a non-significant correlation with age for all age groups. The correlation was moderate and positive except for the SSDE_{AP} Dimension, which had a weak negative correlation with age in age group 4. A weak negative significant correlation was observed between the effective diameter and age in age group 2. In contrast, a moderate, positive, non-significant correlation was observed between the effective diameter and age in age groups 3 and 4.

Table 4.4. Spearman correlation coefficient (r) and p-value for all study variables for age groups.

Variables	Age groups					
	Group 2 [1M - <4Y) (n = 45)		Group 3 [4y - <10Y) (n = 45)		Group 4 [10y - <14Y) (n = 28)	
	r	p-value	r	p-value	r	p-value
CTDI_{vol} (mGy)	0.17522	0.2496 (NS)	0.17078	0.2620 (NS)	0.15812	0.4216 (NS)

DLP (mGy.cm)	0.24983	0.0979 (NS)	0.28600	0.0568 (NS)	0.11377	0.5643 (NS)
SSDE_{AP} Dimension (mGy)	0.13499	0.3766 (NS)	0.20448	0.1779 (NS)	-0.01642	0.9339 (NS)
SSDE_{LAT} Dimension (mGy)	0.08472	0.5800 (NS)	0.12299	0.4209 (NS)	0.13650	0.4885 (NS)
SSDE_{SUM} Dimension (mGy)	0.07422	0.6280 (NS)	0.17145	0.2601 (NS)	0.10685	0.5884 (NS)
SSDE_{Effective Diameter} (mGy)	0.07512	0.6238 (NS)	0.16435	0.2807 (NS)	0.07229	0.7147 (NS)

AP = anterior-posterior, CTDI_{vol} = volume computed tomography dose index, DLP = dose length product, LAT = lateral, mGy = milligray, mGy.cm = milligray per centimetre, M = month, NS = not significant, n = number S = significant, SSDE = size-specific dose estimate, Y = year.

Spearman's correlation coefficient (r) and p-value were also calculated to observe the relationship between all dose quantities in all age groups. Table 4.5 presents the correlation coefficient and p-value, comparing all dose quantities in all the age groups. A strong positive significant correlation was found between all dose quantities in all three age groups.

**Table 4.5.** Spearman correlation coefficient (r) and p-value comparing all dose quantities in all age groups.

Age group 2 [1M - <4Y) (n = 45)							
Dose quantities	r and p-value	CTDI _{vol} (mGy)	DLP (mGy.cm)	SSDE _{AP} Dimension (mGy)	SSDE _{LAT} Dimension (mGy)	SSDE _{SUM} Dimension (mGy)	SSDE _{Effective} Diameter (mGy)
CTDI _{vol} (mGy)	r	1.00000	0.74031	0.93427	0.98150	0.97044	0.97527
	p-value	-	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)
DLP (mGy.cm)	r	0.74031	1.00000	0.66983	0.71415	0.70526	0.69597
	p-value	<0.0001 (S)	-	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)
SSDE _{AP} Dimension (mGy)	r	0.93427	0.66983	1.00000	0.93056	0.95955	0.97011
	p-value	<0.0001 (S)	<0.0001 (S)	-	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)
SSDE _{LAT} Dimension (mGy)	r	0.98150	0.71415	0.93056	1.00000	0.98375	0.98375
	p-value	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	-	<0.0001 (S)	<0.0001 (S)
SSDE _{SUM} Dimension (mGy)	r	0.97044	0.70526	0.95955	0.98375	1.00000	0.99117
	p-value	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	-	<0.0001 (S)
SSDE _{Effective} Diameter (mGy)	r	0.97527	0.69597	0.97011	0.98537	0.99117	1.00000
	p-value	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	-

**Table 4.5.** Spearman correlation coefficient (r) and p-value comparing all dose quantities in all age groups (continued).

Age group 3 [4Y - <10Y] (n = 45)							
Dose quantities	r and p-value	CTDI _{vol} (mGy)	DLP (mGy.cm)	SSDE _{AP} Dimension (mGy)	SSDE _{LAT} Dimension (mGy)	SSDE _{SUM} Dimension (mGy)	SSDE _{Effective-Diameter} (mGy)
CTDI _{vol} (mGy)	r		0.84228	0.90992	0.98958	0.97524	0.96559
	p-value	-	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)
DLP (mGy.cm)	r	0.84228		0.68376	0.82691	0.78088	0.75800
	p-value	<0.0001 (S)	-	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)
SSDE _{AP} Dimension (mGy)	r	0.90992	0.68376		0.92570	0.96619	0.97384
	p-value	<0.0001 (S)	<0.0001 (S)	-	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)
SSDE _{LAT} Dimension (mGy)	r	0.98958	0.82691	0.92570		0.98099	0.97226
	p-value	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	-	<0.0001 (S)	<0.0001 (S)
SSDE _{SUM} Dimension (mGy)	r	0.97524	0.78088	0.96619	0.98099		0.99173
	p-value	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	-	<0.0001 (S)
SSDE _{Effective-Diameter} (mGy)	r	0.96559	0.75800	0.97384	0.97226	0.99173	
	p-value	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	-

**Table 4.5.** Spearman correlation coefficient (r) and p-value comparing all dose quantities in all age groups (continued).

Age group 4 [10Y - <14Y) (n = 28)							
Dose quantities	r and p-value	CTDI _{vol} (mGy)	DLP (mGy.cm)	SSDE _{AP} Dimension (mGy)	SSDE _{LAT} Dimension (mGy)	SSDE _{SUM} Dimension (mGy)	SSDE _{Effective} Diameter (mGy)
CTDI _{vol} (mGy)	r		0.93978	0.89488	0.97851	0.99069	0.98139
	p-value	-	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)
DLP (mGy.cm)	r	0.93978		0.88776	0.89038	0.92390	0.92718
	p-value	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)
SSDE _{AP} Dimension (mGy)	r	0.89488	0.88776		0.89257	0.92226	0.94963
	p-value	<0.0001 (S)	<0.0001 (S)	-	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)
SSDE _{LAT} Dimension (mGy)	r	0.97851	0.89038	0.89257		0.98727	0.97578
	p-value	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	-	<0.0001 (S)	<0.0001 (S)
SSDE _{SUM} Dimension (mGy)	r	0.99069	0.92390	0.92226	0.98727		0.99343
	p-value	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	-	<0.0001 (S)
SSDE _{Effective} Diameter (mGy)	r	0.98139	0.92718	0.94963	0.97578	0.99343	
	p-value	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	-

AP = anterior-posterior, CTDI_{vol} = volume computed tomography dose index, DLP = dose length product, LAT = lateral, mGy = milligray, mGy.cm = milligray per centimetre, M = month, NS = not significant, n = number S = significant, SSDE = size-specific dose estimate, Y = year.

4.2.5 Diagnostic reference levels according to patient weight

Local DRL values were also established based on the weight of the paediatric patients for contrast-enhanced abdominal CT examinations based on nephroblastoma. A Shapiro-Wilk test was performed to examine the distribution of variables within the weight groups. To summarise the LDRL values, the Shapiro-Wilk test was used to determine which variables should be used (see Table 4.6). Statistical correlations between variables and weight groups were also calculated using Spearman's correlation coefficients.

Table 4.6. The results of the Shapiro-Wilk test performed on the variables for weight groups.

Variables	Weight groups	
	Group 2 [5 kg - <15 kg] (n = 45)	Group 3 [15 kg - <30 kg] (n = 53)
	p-value	p-value
CTDI _{vol} (mGy)	0.0019 (S)	<0.0001 (S)
DLP (mGy.cm)	0.1742 (NS)	<0.0001 (S)
SSDE _{AP} Dimension (mGy)	<0.0001 (S)	<0.0001 (S)
SSDE _{LAT} Dimension (mGy)	<0.0001 (S)	<0.0001 (S)
SSDE _{SUM} Dimension (mGy)	<0.0001 (S)	<0.0001 (S)
SSDE _{Effective Diameter} (mGy)	<0.0001 (S)	<0.0001 (S)

AP = anterior-posterior, CTDI_{vol} = volume computed tomography dose index, DLP = dose length product, kg = kilogram, LAT = lateral, mGy = milligray, mGy.cm = milligray per centimetre, NS = not significant, n = number, S = significant, SSDE = size-specific dose estimate.

Shapiro-Wilk tests showed that participants' weight distribution in weight group 2 had significant differences for all the variables except for the DLP. As a result, the mean and standard deviation were used to report on the DLP, while the median and IQR were used on the patient measurements, patient age, CTDI_{vol}, SSDE parameters and the effective diameter for weight group 2. For weight group 3, all variables shown in Table 4.6 did not follow a normal distribution; thus, a significant difference was noted. Consequently, the median and IQR were reported for all variables for weight group 3.

The IQRs were reported as the median and the 75th percentile for the dose quantities for the patient weight: CTDI_{vol}, DLP, SSDE_{AP Dimension}, SSDE_{LAT Dimension}, SSDE_{SUM Dimension} and SSDE_{Effective Diameter} to calculate the LDRL values as recommended by the ICRP (2017:45) and EC (2018:14). Table 4.7 presents the LDRL values based on the median and the 75th percentile for the different dose quantities.

Table 4.7. The LDRL values based on the 75th percentile and the median for the CTDI_{vol}, DLP, SSDE_{AP Dimension}, SSDE_{LAT}, SSDE_{SUM Dimension}, and SSDE_{Effective Diameter} for weight groups.

Dose quantities	Weight groups		
	Group 2 [5 kg – <15 kg] (n = 45)	Group 3 [15 kg – <30 kg] (n = 53)	p-value (Kruskal-Wallis test)
	(75 th percentile) median	(75 th percentile) median	
CTDI _{vol} (mGy)	(2.7) 2.4	(3.5) 2.8	<0.0001 (S)
DLP (mGy.cm)	(95.7) 78.4	(162.6) 118.3	<0.0001 (S)
SSDE _{AP Dimension} (mGy)	(5.6) 5.1	(6.8) 5.6	<0.0001 (S)
SSDE _{LAT Dimension} (mGy)	(5.7) 5.1	(6.8) 5.9	<0.0001 (S)
SSDE _{SUM Dimension} (mGy)	(5.7) 5.1	(6.8) 5.9	<0.0001 (S)
SSDE _{Effective Diameter} (mGy)	(5.7) 5.2	(6.9) 5.9	<0.0001 (S)

AP = anterior-posterior, CTDI_{vol} = volume computed tomography dose index, DLP = dose length product, kg = kilogram, LAT = lateral, mGy = milligray, mGy.cm = milligray per centimetre, NS = not significant, n = number, S = significant, SSDE = size-specific dose estimate

A Kruskal-Wallis test was also performed based on the median of the dose quantities to determine if the weight group of the patients influenced the dose quantities. The p-value results from the Kruskal-Wallis test indicated that there was a significant difference between all weight groups.

4.2.5.1 Correlation analyses of dose quantities based on patient weight

The correlation between the study variables and weight groups was analysed using Spearman's correlation coefficient (r) and p-value. All variables' correlation coefficients and p-values with regard to weight groups are presented in Table 4.8. All other study variables had a non-significant correlation with weight for weight group 2. A weak negative correlation was observed between patient weight and dose quantities ($CTDI_{vol}$; DLP and SSDE parameters) for weight group 2. For weight group 3, the correlation was significant between the patient weight and all study variables for weight group 3. All study variables had a strong positive correlation with patient weight for weight group 3.

Table 4.8. Spearman correlation coefficient (r) and p-value for all study variables for weight groups.

Variables	Weight groups			
	Group 2 [5 kg - <15 kg] (n = 45)		Group 3 [15 kg - <30 kg] (n = 53)	
	r	p-value	r	p-value
$CTDI_{vol}$ (mGy)	-0.03767	0.8059 (NS)	0.70528	<0.0001 (S)
DLP (mGy.cm)	-0.03534	0.8177 (NS)	0.70155	<0.0001 (S)
$SSDE_{AP}$ Dimension (mGy)	-0.05174	0.7357 (NS)	0.70802	<0.0001 (S)
$SSDE_{LAT}$ Dimension (mGy)	-0.12870	0.3995 (NS)	0.69058	<0.0001 (S)
$SSDE_{SUM}$ Dimension (mGy)	-0.07302	0.6336 (NS)	0.70908	<0.0001 (S)
$SSDE_{Effective}$ Diameter (mGy)	-0.07503	0.6242 (NS)	0.69896	<0.0001 (S)

AP = anterior-posterior, $CTDI_{vol}$ = volume computed tomography dose index, DLP = dose length product, kg = kilogram, LAT = lateral, mGy = milligray, mGy.cm = milligray per centimetre, NS = not significant, n = number, S = significant, SSDE = size-specific dose estimate.

Spearman's correlation coefficient (r) and p-value were also calculated to show if there was a relationship between all dose quantities across all weight groups. As shown in Table 4.9, all dose quantities are correlated, and p-values were calculated for each weight group. Each dose quantity in all weight groups showed a strong positive, significant correlation.

**Table 4.9.** Spearman correlation coefficient (r) and p-value comparing all dose quantities in all weight groups.

Group 2 [5kg - <15kg] (n = 45)							
Dose quantities	r and p-value	CTDI _{vol} (mGy)	DLP (mGy.cm)	SSDE _{AP} Dimension (mGy)	SSDE _{LAT} Dimension (mGy)	SSDE _{SUM} Dimension (mGy)	SSDE _{Effective} Diameter (mGy)
CTDI _{vol} (mGy)	r		0.71081	0.91638	0.97956	0.96998	0.96771
	p-value	-	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)
DLP (mGy.cm)	r	0.71081		0.57854	0.68187	0.65391	0.64068
	p-value	<0.0001 (S)	-	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)
SSDE _{AP} Dimension (mGy)	r	0.91638	0.57854		0.92296	0.95939	0.96708
	p-value	<0.0001 (S)	<0.0001 (S)	-	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)
SSDE _{LAT} Dimension (mGy)	r	0.97956	0.71415	0.92296		0.97894	0.97940
	p-value	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	-	<0.0001 (S)	<0.0001 (S)
SSDE _{SUM} Dimension (mGy)	r	0.96998	0.65391	0.95939	0.97894		0.98612
	p-value	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	-	<0.0001 (S)
SSDE _{Effective} Diameter (mGy)	r	0.96771	0.64068	0.96708	0.97940	0.98612	
	p-value	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	-

**Table 4.9.** Spearman correlation coefficient (r) and p-value comparing all dose quantities in all weight groups (continued).

Group 3 [15kg - <30kg] (n = 53)							
Dose quantities	r and p-value	CTDI _{vol} (mGy)	DLP (mGy.cm)	SSDE _{AP} Dimension (mGy)	SSDE _{LAT} Dimension (mGy)	SSDE _{SUM} Dimension (mGy)	SSDE _{Effective} Diameter (mGy)
CTDI _{vol} (mGy)	r		0.85694	0.93993	0.99030	0.98222	0.97611
	p-value	-	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)
DLP (mGy.cm)	r	0.85694		0.78120	0.84265	0.83654	0.82500
	p-value	<0.0001 (S)	-	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)
SSDE _{AP} Dimension (mGy)	r	0.93993	0.78120		0.94520	0.97659	0.98048
	p-value	<0.0001 (S)	<0.0001 (S)	-	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)
SSDE _{LAT} Dimension (mGy)	r	0.99030	0.84265	0.94520		0.98522	0.98032
	p-value	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	-	<0.0001 (S)	<0.0001 (S)
SSDE _{SUM} Dimension (mGy)	r	0.98222	0.83654	0.97659	0.98522		0.99567
	p-value	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	-	<0.0001 (S)
SSDE _{Effective} Diameter (mGy)	r	0.97611	0.82500	0.98048	0.98032	0.99567	
	p-value	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	-

AP = anterior-posterior, CTDI_{vol} = volume computed tomography dose index, DLP = dose length product, kg = kilogram, LAT = lateral, mGy = milligray, mGy.cm = milligray per centimetre, NS = not significant, n = number, S = significant, SSDE = size-specific dose estimate.

4.2.6 Diagnostic reference levels according to the patient's effective diameter

The Shapiro-Wilk test was performed to investigate the distribution of variables for the effective diameter groups, as seen in Table 4.10. The Shapiro-Wilk tests indicated that the distribution of the effective diameter of participants in effective diameter group 2 had significant differences for the majority of the variables, except for the $CTDI_{vol}$ and the $SSDE_{Effective\ Diameter}$. As a result, the mean and standard deviation were used to report on the $CTDI_{vol}$ and $SSDE_{Effective\ Diameter}$, whereas the median and IQR were used to report on the DLP and SSDE parameters (AP dimension, LAT dimension, and Sum dimension) for the effective diameter group 2. The distribution of the effective diameter of participants for effective diameter group 3 was significant. Hence, the mean and standard deviation were used to report on the patient weight, while the median and IQR were used to report on the DLP, $CTDI_{vol}$, and all SSDE parameters.

Table 4.10. Results of the Shapiro-Wilk test performed on the variables for the effective diameter groups.

Variables	Effective diameter groups	
	Group 2 [13 cm - <16 cm] (n = 71)	Group 3 [16 cm - <20 cm] (n = 35)
	p-value	p-value
$CTDI_{vol}$ (mGy)	0.0946 (NS)	0.0309 (S)
DLP (mGy.cm)	0.0002 (S)	0.0453 (S)
$SSDE_{AP\ Dimension}$ (mGy)	0.0358 (S)	0.0118 (S)
$SSDE_{LAT\ Dimension}$ (mGy)	0.0325 (S)	0.0082 (S)
$SSDE_{SUM\ Dimension}$ (mGy)	0.0335 (S)	0.0312 (S)
$SSDE_{Effective\ Diameter}$ (mGy)	0.0520 (NS)	0.0109 (S)

AP = anterior-posterior, cm = centimetre, $CTDI_{vol}$ = volume computed tomography dose index, DLP = dose length product, LAT = lateral, mGy = milligray, mGy.cm = milligray per centimetre, NS = not significant, n = number, S = significant, SSDE = size-specific dose estimate.

As recommended by the ICRP (2017:45) and the EC (2018:14), the IQR was calculated as the median and 75th percentile for $CTDI_{vol}$, DLP, $SSDE_{AP\ Dimension}$, $SSDE_{LAT\ Dimension}$, $SSDE_{SUM\ Dimension}$, and $SSDE_{Effective\ Diameter}$. In Table 4.11, LDRL values based on median and 75th percentile values are presented for the two effective diameter groups.

Table 4.11. The LDRL values based on the 75th percentile and the median for the CTDI_{vol}, DLP, SSDE_{AP} Dimension, SSDE_{LAT}, SSDE_{SUM} Dimension, and SSDE_{Effective Diameter} for two effective diameter groups.

Dose quantities	Effective diameter groups		
	Group 2 [13 cm - <16 cm] (n = 71)	Group 3 [16 cm - <20 cm] (n = 35)	p-value (Kruskal-Wallis test)
	(75 th percentile) median	(75 th percentile) median	
CTDI_{vol} (mGy)	(2.8) 2.4	(6.5) 5.2	<0.0001 (S)
DLP (mGy.cm)	(111.8) 86.2	(325.9) 227.8	<0.0001 (S)
SSDE_{AP} Dimension (mGy)	(5.9) 5.1	(12.2) 10.2	<0.0001 (S)
SSDE_{LAT} Dimension (mGy)	(6.0) 5.2	(11.6) 9.8	<0.0001 (S)
SSDE_{SUM} Dimension (mGy)	(6.1) 5.2	(11.9) 9.9	<0.0001 (S)
SSDE_{Effective Diameter} (mGy)	(6.0) 5.2	(11.7) 9.8	<0.0001 (S)

AP = anterior-posterior, cm = centimetre, CTDI_{vol} = volume computed tomography dose index, DLP = dose length product, LAT = lateral, mGy = milligray, mGy.cm = milligray per centimetre, NS = not significant, n = number, S = significant, SSDE = size-specific dose estimate.

To determine whether the effective diameter groups of the patients influenced the dose quantities, a Kruskal-Wallis test was performed on the median of the dose quantities. The Kruskal-Wallis test p-values (see Table 4.11) illustrate that all weight groups were significantly different.

4.2.6.1 Correlation analyses of dose quantities based on patient effective diameter

To examine the relationship between the study variables and the effective diameter groups, Spearman's correlation coefficient (r) and p-value were calculated. Spearman's correlation coefficient calculations showed that the patient's weight has a positive, moderate, significant correlation with both effective diameter groups, as seen in Table 4.12. A moderate positive correlation, which is non-significant, was observed between $CTDI_{vol}$ and effective diameter group 2. The DLP had a weak positive, significant correlation with effective diameter group 2. Both the dose quantities ($CTDI_{vol}$ and DLP) had a weak negative correlation, which was significant for effective diameter group 3. All the SSDE parameters had a weak, positive, non-significant correlation for effective diameter group 2 and a weak, positive, significant correlation for effective diameter group 3.

Table 4.12. The results of the Spearman correlation coefficient (r) and the p-value calculations performed on the variables for the effective diameter groups.

Variables	Effective diameter groups			
	Group 2 [13 cm - <16 cm] (n = 71)		Group 3 [16 cm - <20 cm] (n = 35)	
	p-value	r	p-value	r
$CTDI_{vol}$ (mGy)	0.0659 (NS)	0.21952	<0.0001 (S)	0.62426
DLP (mGy.cm)	0.0438 (S)	0.24003	<0.0001 (S)	0.65879
$SSDE_{AP}$ Dimension (mGy)	0.4693 (NS)	0.08727	0.0007 (S)	0.54457
$SSDE_{LAT}$ Dimension (mGy)	0.4114 (NS)	0.09901	0.0005 (S)	0.55990
$SSDE_{SUM}$ Dimension (mGy)	0.4338 (NS)	0.09437	0.0004 (S)	0.56817
$SSDE_{Effective\ Diameter}$ (mGy)	0.4883 (NS)	0.08359	0.0004 (S)	0.56483

AP = anterior-posterior, cm = centimetre, $CTDI_{vol}$ = volume computed tomography dose index, DLP = dose length product, LAT = lateral, mGy = milligray, mGy.cm = milligray per centimetre, NS = not significant, n = number, S = significant, SSDE = size-specific dose estimate.

Spearman's correlation coefficient (r) and p-value were calculated to examine the relationship between all dose quantities for all effective diameter groups. The correlation coefficient and p-value for all dose quantities for all effective diameter



groups are shown in Table 4.13. There was a strong, positive, significant correlation between all dose quantities for all effective diameter groups.

**Table 4.13.** Spearman correlation coefficient (r) and p-value comparing all dose quantities for two effective diameter groups.

Group 2 [13 cm - <16 cm] (n = 71)							
Dose quantities	r and p-value	CTDI _{vol} (mGy)	DLP (mGy.cm)	SSDE _{AP} Dimension (mGy)	SSDE _{LAT} Dimension (mGy)	SSDE _{SUM} Dimension (mGy)	SSDE _{Effective} Diameter (mGy)
CTDI _{vol} (mGy)	r		0.68460	0.97361	0.97684	0.98382	0.98171
	p-value	-	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)
DLP (mGy.cm)	r	0.68460		0.64237	0.68187	0.66557	0.64468
	p-value	<0.0001 (S)	-	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)
SSDE _{AP} Dimension (mGy)	r	0.97361	0.64237		0.95788	0.97526	0.98048
	p-value	<0.0001 (S)	<0.0001 (S)	-	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)
SSDE _{LAT} Dimension (mGy)	r	0.97684	0.66115	0.95788		0.98912	0.98663
	p-value	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	-	<0.0001 (S)	<0.0001 (S)
SSDE _{SUM} Dimension (mGy)	r	0.98382	0.66557	0.97526	0.98912		0.98838
	p-value	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	-	<0.0001 (S)
SSDE _{Effective} Diameter (mGy)	r	0.98171	0.64468	0.98048	0.98663	0.98838	
	p-value	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	-



Table 4.13. Spearman correlation coefficient (r) and p-value comparing all dose quantities for two effective diameter groups (continued).

Group 3 [16 cm - <20 cm] (n = 35)							
Dose quantities	r and p-value	CTDI _{vol} (mGy)	DLP (mGy.cm)	SSDE _{AP} Dimension (mGy)	SSDE _{LAT} Dimension (mGy)	SSDE _{SUM} Dimension (mGy)	SSDE _{Effective} Diameter (mGy)
CTDI _{vol} (mGy)	r		0.95299	0.98914	0.98767	0.98823	0.99468
	p-value	-	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)
DLP (mGy.cm)	r	0.95299		0.94340	0.92469	0.94067	0.93703
	p-value	<0.0001 (S)	-	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)
SSDE _{AP} Dimension (mGy)	r	0.98914	0.94340		0.98046	0.98942	0.99335
	p-value	<0.0001 (S)	<0.0001 (S)	-	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)
SSDE _{LAT} Dimension (mGy)	r	0.98767	0.92469	0.98046		0.98403	0.98907
	p-value	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	-	<0.0001 (S)	<0.0001 (S)
SSDE _{SUM} Dimension (mGy)	r	0.98823	0.94067	0.98942	0.98403		0.99019
	p-value	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	-	<0.0001 (S)
SSDE _{Effective} Diameter (mGy)	r	0.99468	0.93703	0.99335	0.98907	0.99019	
	p-value	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	<0.0001 (S)	-

AP = anterior-posterior, cm = centimetre, CTDI_{vol} = volume computed tomography dose index, DLP = dose length product, LAT = lateral, mGy = milligray, mGy.cm = milligray per centimetre, NS = not significant, n = number, S = significant, SSDE = size-specific dose estimate.

4.2.7 Comparison of diagnostic reference levels - weight versus effective diameter

Comparing the paediatric LDRL values calculated using the weight versus the effective diameter of the patient, was one of the objectives of this study. The results of the comparisons will determine whether the patient's effective diameter or weight of the patient is more reliable for setting paediatric LDRL values. Table 4.14 illustrates the paediatric LDRL values based on the patient's weight and effective diameter.

Table 4.14. Comparison of paediatric LDRL values based on the 75th percentile and the median calculated using weight versus the effective diameter of the patient.

Dose quantities	Weight groups		Effective diameter groups	
	Group 2 [5 kg – <15 kg] (n = 45)	Group 3 [15 kg – <30 kg] (n = 53)	Group 2 [13 cm - <16 cm] (n = 71)	Group 3 [16 cm - <20 cm] (n = 35)
	(75 th percentile) median	(75 th percentile) median	(75 th percentile) median	(75 th percentile) median
CTDI_{vol} (mGy)	(2.7) 2.4	(3.5) 2.8	(2.8) 2.4	(6.5) 5.2
DLP (mGy cm)	(95.7) 78.4	(162.6) 118.3	(111.8) 86.2	(325.9) 227.8
SSDE_{AP} Dimension (mGy)	(5.6) 5.1	(6.8) 5.6	(5.9) 5.1	(12.2) 10.2
SSDE_{LAT} Dimension (mGy)	(5.7) 5.1	(6.8) 5.9	(6.0) 5.2	(11.6) 9.8
SSDE_{SUM} Dimension (mGy)	(5.7) 5.1	(6.8) 5.9	(6.1) 5.2	(11.9) 9.9
SSDE_{Effective Diameter} (mGy)	(5.7) 5.1	(6.9) 5.9	(6.0) 5.2	(11.7) 9.8

AP = anterior-posterior, cm = centimetre, CTDI_{vol} = volume computed tomography dose index, DLP = dose length product, kg = kilogram, LAT = lateral, mGy = milligray, mGy.cm = milligray per centimetre, NS = not significant, n = number, S = significant, SSDE = size-specific dose estimate.

The Kruskal-Wallis test was also performed to observe the differences between the LDRL values in weight and effective diameter groups. The Kruskal-Wallis test indicated a significant difference (p-value ≤ 0.0001) between paediatric LDRL values in weight groups and paediatric LDRL values in the effective diameter groups.

4.2.8 Diagnostic reference levels for the whole sample size

The Shapiro-Wilk test was used to investigate the distribution of dose quantities for the whole study sample. The Shapiro-Wilk tests indicated that the distribution of $CTDI_{vol}$ for all study participants had a significant difference (p -value < 0.0001) for all the SSDE parameters. As a result, the median and 75th percentile were used to report on the $CTDI_{vol}$ and SSDE parameters for the whole sample size (see Table 4.15).

Table 4.15. LDRL values based on the median and the 75th percentile for the $CTDI_{vol}$, DLP, $SSDE_{AP}$ Dimension, $SSDE_{LAT}$ Dimension, $SSDE_{SUM}$ Dimension and $SSDE_{Effective}$ Diameter for the whole study sample ($n = 120$).

Dose quantities	Median	75 th percentile
$CTDI_{vol}$ (mGy)	2.7	4.1
$SSDE_{AP}$ Dimension (mGy)	5.6	7.8
$SSDE_{LAT}$ Dimension (mGy)	5.8	7.9
$SSDE_{SUM}$ Dimension (mGy)	5.7	7.8
$SSDE_{Effective}$ Diameter (mGy)	5.7	7.7

AP = anterior-posterior, $CTDI_{vol}$ = volume computed tomography dose index, DLP = dose length product, LAT = lateral, mGy = milligray, mGy.cm = milligray per centimetre, SSDE = size-specific dose estimate.

To investigate if there was a significant difference between the 75th percentile of $CTDI_{vol}$ and all SSDE parameters, the difference was calculated and then used to calculate the confidence limits. Table 4.16 presents the confidence limits calculated between the 75th percentile of $CTDI_{vol}$ and SSDE parameters for the whole sample. There was a significant difference between the 75th percentile of $CTDI_{vol}$ and SSDE parameters, as is evident in Table 4.16, where zero is not included in the interval/ranges.

Table 4.16. The confidence limits for comparison of the 75th percentile of CTDI_{vol} and SSDE parameters for the whole sample size (n = 120).

95% Confidence limits		
	Ranges	
SSDE_{AP} Dimension (mGy) vs CTDI_{vol} (mGy)	3.3	4.6
SSDE_{LAT} Dimension (mGy) vs CTDI_{vol} (mGy)	3.4	4.7
SSDE_{SUM} Dimension (mGy) vs CTDI_{vol} (mGy)	3.4	4.9
SSDE_{Effective-Diameter} (mGy) vs CTDI_{vol} (mGy)	3.5	4.8

AP = anterior-posterior, CTDI_{vol} = volume computed tomography dose index, DLP = dose length product, LAT = lateral, mGy = milligray, mGy.cm = milligray per centimetre, SSDE = size-specific dose estimate.

Spearman's correlation coefficient (r) and p-value were also calculated to investigate the relationship between patient age and weight for all dose quantities in the whole study sample. Table 4.17 presents the correlation coefficient and p-value, comparing patient age and weight of all dose quantities in the study sample. A strong positive, non-significant correlation were found between patient age and weight for all dose quantities in the study sample.

Table 4.17. Spearman correlation coefficient (r) and p-value between patient age and weight for the whole study sample (n = 120).

Dose quantities	Age years (r)	Patient weight (r)	p-value
CTDI_{vol} (mGy)	0.66031	0.71376	0.4354 (NS)
SSDE_{AP} Dimension (mGy)	0.61932	0.65895	0.6101 (NS)
SSDE_{LAT} Dimension (mGy)	0.58546	0.64962	0.4295 (NS)
SSDE_{SUM} Dimension (mGy)	0.60886	0.66082	0.5029 (NS)
SSDE_{Effective Diameter} (mGy)	0.59777	0.65591	0.4654 (NS)

AP = anterior-posterior, CTDI_{vol} = volume computed tomography dose index, DLP = dose length product, LAT = lateral, mGy = milligray, mGy.cm = milligray per centimetre, NS = not significant, SSDE = size-specific dose estimate.

4.2.9 The diagnostic reference levels in this study in relation to diagnostic reference levels developed in other studies

The paediatric LDRLs developed in this study were also compared with DRL values developed in international studies. A comparison between LDRLs developed in this study and international studies is illustrated in Table 4.18.

Table 4.18. The DRL values based on the 75th percentile and median of this research study in relation to DRL values published studies for CT abdomen-pelvis examinations for paediatric patients.

Research Study	Clinical indication	NDRLs/ RDRLs/ LDRLs/ Typical DRLs	Weight groups (kg)	Age groups (months/ years)	Effective diameter groups (cm)	(75 th percentile) and/or median					
						CTDI _{vol} (mGy)	DLP (mGy.cm)	SSDE _{AP} Dimension (mGy)	SSDE _{LAT} Dimension (mGy)	SSDE Effective Diameter (mGy)	SSDE _{SUM} Dimension (mGy)
						(75 th percentile) Median	(75 th percentile) Median	(75 th percentile) Median	(75 th percentile) Median	(75 th percentile) Median	(75 th percentile) Median
This study (2024)	Nephroblastoma	LDRLs	[5 kg - <15 kg) (n = 45)	-		(2.7) 2.4	(95.7) 78.4	(5.6) 5.1	(5.7) 5.1	(5.7) 5.1	(5.7) 5.1
			[15 kg - <30 kg) (n = 53)	-		(3.5) 2.8	(162.6) 118.3	(6.8) 5.6	(6.8) 5.9	(6.9) 5.9	(6.8) 5.9
				[1M - <4Y) (n = 45)	-	(2.7) 2.4	(98.7) 81.4	(5.6) 5.1	(5.8) 5.1	(5.8) 5.2	(5.8) 5.1
				[4Y - <10Y) (n = 45)	-	(3.1) 2.6	(131.9) 112.8	(6.3) 5.4	(6.6) 5.4	(6.4) 5.5	(6.4) 5.5
				[10Y - <14Y) (n = 28)	-	(7.1) 5.8	(367.9) 262.5	(12.5) 10.3	(12.7) 10.9	(12.8) 11.1	(12.7) 10.8
					[13 cm - <16 cm) (n = 71)	(2.8) 2.4	(111.8) 86.2	(5.9) 5.1	(6.0) 5.2	(6.0) 5.2	(6.1) 5.2
					[16 cm - <20 cm) (n = 35)	(6.5) 5.2	(325.9) 227.8	(12.2) 10.2	(11.6) 9.8	(11.7) 9.8	(11.9) 9.9
Imai et al. (2015)[#]	N/I	LDRLs	-	1 year	-	3.5	133.6	-	-	-	3.6
			-	5 years	-	1.9	97.4	-	-	-	4.2
			-	10 years	-	2.9	167.0	-	-	-	5.4
			-	<15 years	-	9.0	680.8	-	-	-	14.4
Bibbo et al. (2016)	N/I	NDRLs	0–7 kg (n = 13)	-	-	(4.0)	(126)	-	-	-	-



			>7–11 kg (n = N/A)	-	-	-	-	-	-	-	-
			>11–22 kg (n = 88)	-	-	(2.0)	(91)	-	-	-	-
			>22–40 kg (n = 79)	-	-	(4.0)	(221)	-	-	-	-
			>40–55 kg (n = 58)	-	-	(7.0)	(459)	-	-	-	-
			>55–80 kg (n = 36)	-	-	(7.0)	(461)	-	-	-	-
			80 kg (n = 13)	-	-	(12.0)	(828)	-	-	-	-
			-	<5 years (n = 33)		(2.4)	(74.0)	-	-	-	-
			-	5–10 years (n = 73)		(4.7)	(168.0)	-	-	-	-
			-	>10 years (n = 241)		(7.0)	(365.0)	-	-	-	-
European Commission (2018)	N/I	NDRLs	<5 kg (n = N/A)	-	-		45	-	-	-	-
			5 - <15 kg (n = N/A)	-	-	3.5	120.0	-	-	-	-
			15 - <30 kg (n = N/A)	-	-	5.4	150.0	-	-	-	-
			30 - <50 kg (n = N/A)	-	-	7.3	210	-	-	-	-
			50 - <80 kg (n = N/A)	-	-	13	480	-	-	-	-
Muhammad et al. (2020)	N/I	LDRLs	-	(0 - <1Y) (n = 7)		(3.0) 3.0	(116.0) 98.1	-	-	-	-
			-	(1Y - <5Y) (n = 95)		(6.0) 4.6	204.0 (150.2)	-	-	-	-
			-	(5Y - <10Y) (n = 94)		(11.0) 7.1	(419.0) 292.6	-	-	-	-
			-	(10Y - <15Y) (n = 110)		(16.0) 11.7	(911.0) 644.9	-	-	-	-
Hwang et al. (2021)*	N/I	Typical DRLs	<5 kg (n = 17)	1M (n = 17)		(1.4) 1.4	(30.0) 24.1	-	-	-	(3.7) 3.5



			5 - <15 kg (n = 259)	11M - <4 Y (n = 259)		(2.2) 1.9	(73.8) 59.9	-	-	-	(4.8) 4.1
			15 - <30 kg (n = 520)	4Y - <10Y (n = 520)		(2.7) 2.3	(101.2) 94.1	-	-	-	(5.5) 4.2
			30 - <50 kg (n = 496)	10Y - <14Y (n = 496)		(4.0) 2.6	(168.8) 121.1	-	-	-	(6.6) 4.4
			50 - <80 kg (n = 333)	14Y - <18Y (n = 333)		(4.7) 3.7	(233.0) 179.8	-	-	-	(7.3) 5.6
				-	<13 cm (n = 61)	1.4 (1.8)	32.0 (46.2)	-	-	-	3.5 (4.1)
				-	14–16 cm (n = 7)	1.9 (2.3)	66.5 (79.0)	-	-	-	4.0 (5.0)
				-	17–20 cm (n = 7)	2.2 (3.0)	107.6 (112.6)	-	-	-	4.1 (5.7)
				-	21–24 cm (n = 7)	2.9 (4.3)	153.9 (190.5)	-	-	-	4.8 (7.1)
				-	>24 cm (n = 7)	3.9 (5.0)	201.4 (238.2)	-	-	-	6.0 (7.2)
				-	-	-	-	-	-	-	-
Almén et al. (2022)	Tumour and infection	RDRLs	15 - <30 kg (n = 60)	-	-	2.6	91.7	-	-	-	-
			30 - <50 kg (n = 82)	-	-	3.4	150	-	-	-	-
			50 - <70 kg (n = 57)	-	-	5.0	247	-	-	-	-
Satharasinghe et al. (2022)	N/I	NDRLs	-	(0 - 1Y) (n = 47)	-	(4.5) 3.8	(143.5) 103	-	-	(11.0) 9.1	-
			-	(1Y - <5Y) (n = 43)	-	(6.1) 4.1	(142.0) 103	-	-	(13.5) 9.1	-
			-	(5Y - <10Y) (n = 51)	-	(10.3) 6.5	(247.0) 221	-	-	(19.6) 13.6	-
			-	(10Y - <15Y) (n = 69)	-	(11.9) 10.3	(603.0) 436	-	-	(22.1) 19.5	-
			-	-	0–14.5 cm	4.1 (5.2)	115 (142)	-	-	9.1 (12.6)	-
			-	-	14.5–18.0 cm	8.9 (11.3)	247 (436)	-	-	17.2 (21.9)	-



			-	-	18.0–22.0 cm	10.3 (10.6)	436 (436)	-	-	18.8 (19.6)	-
			-	-	22.0–25.0 cm	16.1 (17.6)	605 (606)	-	-	25.2 (26.7)	-

AP = anterior-posterior, cm = centimetre, CTDI_{vol} = volume computed tomography dose index, DLP = dose length product, kg = kilogram, LAT = lateral, LDRLs = local diagnostic reference levels, mGy = milligray, mGy.cm = milligray per centimetre, M = month, N/A = not available, NDRLs = national diagnostic reference levels, N/I = not indicated, RDRLs = regional diagnostic reference levels, SSDE = size-specific dose estimate, Y = years, *Hwang et al. (2021) did not have DRL values for age and weight separately. The specific SSDE parameter for the study conducted by Hwang et al. (2021) was not indicated. #The specific SSDE parameter for the study conducted by Imai et al. (2015) was not indicated.

4.3 DISCUSSION

This is the first study that has established paediatric LDRL values based on nephroblastoma for paediatrics in South Africa and internationally, based on all the SSDE parameters, as seen in Table 4.18. For this study, paediatric LDR values were calculated based on the age, weight and effective diameter of the patient as recommended by the ICRP (2017), EC (2018) and Hwang et al. (2021:1174), respectively, based on the dose quantity SSDE (AAPM, 2011:18). The LDRL values in this study are presented as the median and 75th percentile of the various dose quantities (SSDE_{AP Dimension}, SSDE_{LAT Dimension}, SSDE_{SUM Dimension} and SSDE_{Effective Diameter}) for CT. The total CTDI_{vol} was used in this study to calculate the SSDE, using the respective conversion factors as published by the AAPM since all selected CT scans were performed in a single phase.

The GE Healthcare CT unit used for the CT scanning of participants involved in this study uses the ATCM (SmartmA and AutomA) and the IR algorithm, ASIR. By using SmartmA, the tube current is automatically adjusted based on the patient's size and attenuation level to maintain a user-defined noise level (Bruesewitz et al., 2008:2). According to the ICRP (2017:18), the ATCM reduces patient dose by 30 to 40% per scan sequence, which results in a significantly lower patient dose (ICRP, 2017:81). The ATCM reduces the dose by determining the estimated contrast-to-noise ratio (CNR) for the anatomy of interest. Furthermore, the ATCM selects the exposure setting that results in a similar CNR at the lowest radiation dose (Papadakis & Damilakis, 2019:265). The IR also reduces the patient dose when applied to scanning protocols, as the ICRP (2017:32) stated that these reconstruction algorithms permit CT acquisition at a lower patient dose. The IR used in this study is ASIR, which reduces image noise, allowing for less ionising radiation to be used during CT scans without compromising image quality (Maxfield, Schuster, McGillicuddy, Young, Ghita, Bokhari, Oliva, Brink & Davis, 2012:1). Therefore, due to the use of ATCM and IR, CT scans of participants involved in this study were performed at a relatively low radiation dose with acceptable image quality.

The annual QC tests performed on the participants involved in this study adhered to all the recommended requirements for the CT unit at the participating imaging department. The annual QC tests are executed to ensure that the equipment is functioning acceptably and that it is providing clinical images of diagnostic quality acceptable for the clinical task (ICRP, 2017:61). The dosimetric quantity from the CT unit at the participating imaging department was accurate since the CT unit was calibrated through daily, monthly and annual QC tests to ensure that it is functioning acceptably; therefore, the paediatric LDRL values developed in this study are reliable.

This study was conducted retrospectively by collecting dose quantities ($CTDI_{vol}$ and DLP), patient weight and radiology reports from the PACS/CT computer console and CT register. A radiologist employed at the participating imaging department reported on all the CT examinations that formed part of this study. Even though the image quality was not assessed in this study, it is presumed that it was optimal for diagnosis.

Several parameters were considered when developing the paediatric LDRLs due to their impact on radiation dose. These parameters are discussed briefly in Chapter 2 (see section 2.2.3.2), including kVp, mAs, gantry rotation time, section thickness, pitch, distance of X-ray tube to CT isocenter and scan length. With the use of ATCM and IR, these parameters were set automatically, and they were not kept constant for all patients; they were different for each patient. Therefore, the radiation impact of these parameters on patients participating in this study was not studied in detail.

The 120 patients that formed part of this study were categorised into five age groups, five weight groups and five effective diameter groups, according to the international guidelines (see Figures 4.1, 4.2 and 4.3), the ICRP (2017:93), the EC (2018:33) and Hwang et al. (2021:1174). As stated by the ICRP (2017:82), a minimum of 20 to 30 patients are required per group to establish DRL values when the data are collected using a paper form. Thus, paediatric LDRL values in this study were developed for only two weight groups and three age groups because these groups included the minimum number of patients specified and, therefore, adhered to the guidelines of the ICRP when establishing DRL values.

Studies conducted by Hwang et al. (2021:1183) and Almén et al. (2022:9) could not calculate paediatric DRL values for the different age and weight groups because of insufficient data. In the study by Hwang et al. (2021:1178), the sample size of the weight band in weight of 5 kg, effective diameter <13 cm, and age band of 0 years were insufficient to develop the typical values. In the study of Almén et al. (2022:4), it was stated that patient data were lacking in the lightest weight group (<5 kg) and heaviest weight group (50 kg–70 kg). The lack of data in groups of older patients in this study could be because nephroblastoma is the most common malignant tumour in children aged one to five (Varan, 2008:84). Therefore, the data obtained for the respective age and weight groups in this study compare well with other studies.

Hwang et al. (2021:1183) and Almén et al. (2022:9) state that it is quite difficult to gather substantial data when developing DRL values for paediatric patients. Furthermore, collecting paediatric data based on clinical indication requires a longer time to ensure that there is a good sample for the respective age and weight groups (Almén et al., 2022:9). Almén et al. (2022:9) further stated that collecting paediatric data that includes clinical indications requires a longer time, and even collecting sufficient data for predefined indications for adult examinations has proved to be a challenge. The data challenges experienced by other authors were evident in this study as well. Because of a lack of data, paediatric LDRL values were established only for two weight groups (weight group 2 [5 kg to <15 kg), weight group 3 [15 kg to <30 kg)) and three age groups (age group 2 [1M to <4Y), age group 3 [4Y to <10Y) and age group 4 [10Y to <14Y)).

The age of the patients has been used in the past to define groups for paediatric DRL values. An analysis of age alone has shown that it is not a reliable indicator. Therefore, it is preferable to use weight categories whenever possible (ICRP, 2017:92). The AAPM introduced SSDE, an estimate of the patient dose that includes patient size corrections to assess the patient dose more accurately (AAPM, 2011:18). The ICRP (2017:92) also stated that the amount of radiation used for examinations of children varies considerably, according to their size and weight. Therefore, the ICRP (2017:92) recommends that dose estimates based on a patient's size be used when available (see section 2.2.5.2). The paediatric LDRL values developed in this study are

categorised according to the age, weight, and effective diameter groups based on the $CTDI_{vol}$ and DLP, which includes the patient size dose quantity SSDE, as suggested by the AAPM (2011:18).

4.3.1 Diagnostic reference levels according to age

The relationship between LDRL values developed in each age group was studied. The Kruskal-Wallis test was also done to observe the difference between LDRL values developed in each age group. The p-value results from the Kruskal-Wallis test indicated that there is a significant difference between the patient age groups based on $CTDI_{vol}$, DLP, $SSDE_{AP\text{ Dimension}}$, $SSDE_{LAT\text{ Dimension}}$, $SSDE_{SUM\text{ Dimension}}$ and $SSDE_{Effective\text{ Diameter}}$. This means the accumulation of radiation dose differs in each age group, thus indicating the need to separate patients according to their age in this study.

Several tests were done to better understand the relationship between patient age groups and variables observed in this study, most importantly, the dose quantities used to develop paediatric LDRL values. The ICRP (2017:57) stated that the 75th percentile and the initial separator between acceptable and excessive values; therefore, the 75th percentile was reported for DLP. As a result, the LDRL values developed for all age groups were based on the 75th percentile, the IQR. This is the same reason for age group 4, where all dose quantities followed a normal distribution, but the 75th percentile was used to set the paediatric LDRL values.

Spearman's correlation test was performed to study the impact of age on the study variables. The results of the Spearman's correlation test indicated that there is no significant correlation between age in all age groups and dose quantities (DLP , $CTDI_{vol}$ and SSDE parameters). Therefore, these findings indicate that patient age does not have a direct relationship with dose quantities since dose quantities decrease and patient age increases. The results found regarding the correlation between age and dose quantities could be affected by the use of ATCM. As mentioned earlier (see section 4.3), the ATCM uses the CNR of an image at a specific surface anatomy to determine the exposure settings required to produce a quality image (Papadakis & Damilakis, 2019:265). Therefore, the radiation dose acquired by the patient is mainly based on the surface anatomy rather than the patient's age. The age and dose

quantities correlation findings in this study are different and opposite from what other authors have concluded. As mentioned earlier, Rawashdeh, Saade, Al Mousa, Abdelrahman, Kumar and McEntee (2023:6) concluded that all dose quantities (DLP, CTDI_{vol} and SSDE) increase with patient age groups. No studies were found where dose quantities decreased when patient age increased. However, the majority of authors, including Hwang et al. (2020:1181), Almén et al. (2022:66) and ICRP (2017:91), suggest that patient size is preferable to age groups when developing paediatric DRL values. As was already mentioned in Chapter 2 (see section 2.2.5.2), the radiation dose received by a patient from a CT scan is a function of their size and the scanner output (AAPM, 2011:2). Therefore, the findings in this study also indicated that age is not a reliable parameter to use when developing paediatric DRL values, since it does not have a significant impact on patient radiation dose.

The relationship between patient age and other variables, such as patient measurements and patient weight, was also explored. Patient age had a significant correlation with patient measurements and weight in weight groups 2 and 3 and a non-significant correlation with age in age group 4. Hwang et al. (2021:1177) also had findings similar to those of age groups 2 and 3, where patient weight strongly correlated with patient age. This means the patient's body size increases with age. However, Almén et al. (2022:69) stated that child growth does not follow a smooth mathematical equation. This supports the reason for a non-significant correlation found in age group 4. Therefore, this still supports the suggestion by ICRP (2017:91) that age categories should only be used if age is the only available measure.

Spearman's correlation test was also performed to study the impact that dose quantities have on other dose quantities (see Table 4.5). There was a strong positive, significant correlation between the dose quantities for all age groups. This means there is a direct relationship between dose quantities in all age groups since dose quantities increase with other dose quantities. Therefore, for all age groups, all dose quantities impact age equally the same. However, this does not conclude that age is an accurate measure, since it was already stated earlier that the radiation impact of dose quantities on age is not significant. Therefore, age categories should not be used if other measures that consider patient size are available, as stated by the ICRP (2017:91).

4.3.2 Diagnostic reference levels according to weight

The paediatric LDRL values developed for weight groups in this study are demonstrated in Table 4.7. The relationship between LDRL values developed in each weight group was examined. Kruskal-Wallis analysis was conducted to determine whether the LDRL values developed by each weight group differed based on the dose quantities. According to Kruskal-Wallis test results, there is a significant difference between patient weight groups. Therefore, patients should be separated based on weight since the radiation dose accumulates differently in each weight group. As a result, paediatric DRL values should be developed for different weight groups as suggested by the EC (2018:32) and ICRP (2017:92).

Several tests were conducted in this study to determine the relationship between patient weight groups and the variables observed, including the dose quantities used to develop paediatric LDRL values. The ICRP (2017:57) defines the 75th percentile as the initial distinction between acceptable and excessive values; therefore, the 75th percentile was used to report on the DLP. Accordingly, all LDRL values developed for weight groups are based on the 75th percentiles, which are the IQR.

A Spearman's correlation test was also conducted to examine how weight groups affect study variables. The DLP, CTDI_{vol}, and SSDE parameters had a non-significant correlation with weight in weight group 2. Based on the results, the radiation dose to the patient is not influenced by the patient's weight for participants in weight group 2. No studies have been found to support the correlation between weight in weight group 2 and dose quantities. The results concerning the correlation between weight in weight group 2 and dose quantities may be influenced by ATCM. As was discussed earlier, in the case of patient age and dose, the ATCM determines exposure settings based on the CNR of an image at the specific surface anatomy (Papadakis & Damilakis, 2019:265). As a result, the radiation dose is primarily determined by the patient's surface anatomy rather than the patient's weight. The DLP, CTDI_{vol}, and SSDE parameters had a significant correlation with weight group 3. This means that the radiation dose increased for participants in weight group 3 as the patient's weight increased. Inoue, Itoh, Nagahara, Hata and Mitsui (2023:1390) also concluded that patient radiation dose was strongly correlated with patient weight, and the dose

quantities ($CTDI_{vol}$ and DLP) increased as the patient weight increased. The ICRP (2017:93) and EC (2018:32) stated that patient weight is the most dependable factor linked to a DRL quantity. Therefore, weight should still be used for categorising, as suggested by the ICRP (2017), but the relationship between patient weight and exposures produced by the ATCM should also be studied.

The effect of dose quantities on other dose quantities was also studied using Spearman's correlation test (see Table 4.9). A positive, significant correlation was found between dose quantities for all weight groups. Consequently, there is a direct relationship between dose quantities in all weight groups since dose quantities increase as other dose quantities decrease. Owing to this, all dose quantities have the same impact on weight for all weight groups.

Patient weight significantly correlated with patient measurements and age in age groups 2 and 3. According to previous studies conducted by Hwang et al. (2021:1183) and Imai et al. (2015:349), which achieved similar results as this study, patient weight strongly correlated with patient measurements. Therefore, this supports the suggestion made by the ICRP (2017:97) that patient size should be used to develop DRL values when the size of the patient, such as the weight, is available. This study used patient weight to categorise patients; thus, the SSDE was used as a dose quantity to develop paediatric LDRL values.

4.3.3 Diagnostic reference levels according to the effective diameter

The paediatric LDRL values established for effective diameter groups in this study are presented in Table 4.11. Kruskal-Wallis analysis was conducted to investigate whether the LDRL values developed by each effective diameter group differed based on the dose quantities. Kruskal-Wallis test results indicate that the patient effective groups differ significantly. Therefore, radiation dose accumulates differently in different effective diameter groups, so it is important to separate patients according to their effective diameter.

A Spearman's correlation test was performed to examine how effective diameter groups affect dose quantities (Table 4.12). The DLP, $CTDI_{vol}$, and SSDE parameters

had a non-significant correlation with effective diameter group 2. Therefore, the radiation dose to the patient is not influenced by the patient's effective diameter for participants in effective diameter group 2. According to ICRP (2017:81), the effective diameter has an impact on the radiation dose since it takes into consideration the size of the patient. Therefore, no studies have been found to support the non-correlation between effective diameter and dose quantities in effective diameter group 2. The reason for the non-correlation between dose quantities and effective diameter group 2 could be the size of patients in effective diameter group 2. However, it has not been proved previously that dose quantities do not affect patients with a 13 cm to <16 cm effective diameter. The DLP, CTDI_{vol}, and SSDE parameters had a significant correlation with effective diameter group 3. This means the radiation dose also increases as the effective diameter increases for participants in effective diameter 3. The study of Cook, Chadalavada and Boom (2013:2) found that effective diameter impacts the radiation dose since the effective diameter represents dimensional measurements at a specific cross-sectional image. For this reason, the effective diameter is considered the most preferable method of categorising paediatric patients when developing DRL values.

The impact of dose quantities on other dose quantities was also studied using Spearman's correlation coefficient test (see Table 4.13). A significant positive correlation was found between dose quantities for all effective diameter groups. As a result, there is a direct relationship between dose quantities in all effective diameter groups since dose quantities increase as other dose quantities decrease. Owing to this, all dose quantities have the same impact on the effective diameter for all effective diameter groups.

4.3.4 Comparison of diagnostic reference levels- weight versus the effective diameter

Statistical tests were done to observe the difference and the relationship between patient weight and effective diameter. The Kruskal-Wallis test showed a significant difference between paediatric LDRL values in weight groups and paediatric LDRL values in effective diameter groups. This is because patient weight does not represent the portion of the anatomy being imaged, and the effective diameter represents

dimensional measurement at a specific cross-sectional image (Cook et al., 2013:2). As a result, the effective diameter becomes the most preferable method of categorising when developing paediatric LDRL values. Spearman's correlation coefficient indicated a weak and moderate correlation between the patient weight and the effective diameter, respectively, for effective diameter groups 2 and 3. However, the correlation was significant for both effective diameter groups. Hwang et al. (2021:1177) and Imai et al. (2015:351) noted a strong correlation between patient weight and the effective diameter. These findings support the statement made by Imai et al. (2015:351) that the effective diameter is a function of patient weight. Furthermore, the ICRP (2017:97) suggested that the effective diameter should be considered an alternative to weight or an additional refinement when developing DRL values.

4.3.5 Diagnostic reference levels for the whole sample size

The paediatric LDRL values developed for the whole study sample in this study are demonstrated in Table 4.15. A significant difference between the $CTDI_{vol}$ and SSDE parameters was noted through a 95% confidence limit (Table 4.16) calculated on the 75th percentile, which indicates that both the dose quantities ($CTDI_{vol}$ and SSDE) have a different impact on the radiation received by the study participants. However, since the $CTDI_{vol}$ provides only information about the scanner's output, it cannot estimate patient doses (AAPM, 2011:2). Therefore, the AAPM (2011:18) suggested that the dose quantity SSDE be used since the SSDE incorporates corrections based on the patient's size.

A strong positive, non-significant correlation between patient age and weight for all dose quantities in the whole study sample was noted using Spearman's correlation coefficient (see Table 4.17). This means the overall weight of all study participants is not comparable to their age. Therefore, as stated by ICRP (2017:91), age alone is not a good indicator for setting paediatric DRL values and should be used if age is the only measure available.

4.3.6 The diagnostic reference levels in this study in relation to diagnostic reference levels developed in other studies

There is a paucity of literature where the paediatric LDRL values were developed specifically for CT contrast studies on paediatrics with a clinical diagnosis of nephroblastoma. The only study found was of Almén et al. (2022:5), where paediatric DRL values were developed for CT abdomen, based on the clinical indications using weight and age to group patients. Almén et al. (2022:5) described the clinical indication studied as tumour or inflammation for CT abdomen. This study provides rare and valuable data by developing paediatric LDRL values based on nephroblastoma using three grouping methods: age groups, weight groups and effective diameter groups. Moreover, the clinically-based paediatric LDRL values were also developed on the CTDI_{vol} and DLP, as well as on the SSDE. In the study of Hwang et al. (2021), SSDE was used to develop paediatric DRLs for age groups, weight groups and effective diameter groups. Satharasinghe et al. (2022) used SSDE for age groups and effective diameter groups, while Imai et al. (2015) used SSDE only for age groups. Despite the use of SSDE by Hwang et al. (2021), Satharasinghe et al. (2022), and Imai et al. (2015), no paediatric DRL values for nephroblastoma have been derived in any of these studies. As seen in Table 4.18, only this study developed DRL values based on a specific clinical indication and all the parameters for the dose quantity SSDE.

Patients receive different radiation doses from CT scans, depending on their size and scanner output (AAPM, 2011:2). In paediatric examinations, the amount of radiation used varies considerably, based on the child's size and weight (ICRP, 2017:92). In this regard, dose estimates based on the patient's size are more precise and should be used whenever that information is available (ICRP, 2017:97). Hence, this study focuses more on the effective diameter and weight as categorising groups and the use of the dose quantity SSDE to compile DRL values.

The paediatric LDRL value in this study is developed for weight group 2 [5kg - < 15kg), weight group 3 [15kg - < 30kg), age group 2 [1M - < 4y), age group 3 [4y - < 10y), age group 4 [10y - <14y), effective diameter group 2 [13 cm to <16 cm), and effective diameter group 3 [16 cm to <20 cm) because each group consisted of a minimum of 20 to 30 patients per category, as suggested by the ICRP (2017:82) to develop DRL

values. The grouping of the patients was based on the EC (2018:33) and the ICRP (2017:92) guidelines. Other authors, such as Strauss, Goske, Towbin, Sengupta, Callahan, Darge, Podberesky, Frush, Maxfield, Westra, Prince, Wu and Bhargavan-Chatfield (2017), Muhammad et al. (2020), Van der Merwe and Mahomed (2020), and Hwang et al. (2021) used the same grouping method suggested by the ICRP (2017:93). The studies of Bibbo, Brown and Linke (2016) and Almén et al. (2022) used age and weight grouping categories that differ from those used by ICRP (2017:82) and other authors. Thus, there were no standardised age groups and weight groups when comparing paediatric DRL values developed in this study with the paediatric DRL values developed by Bibbo et al. (2016) and Almén et al. (2022). Hwang et al. (2021), from which the effective diameter groups were copied, did not develop LDRL values for nephroblastoma patients as mentioned above. Future studies should strictly adhere to the grouping methods suggested by the ICRP (2017:92) and the EC (2018:33) for easier comparison.

For all indicated groups, the LDRL values in this study are lower than the DRL values developed in most international studies for paediatric CT abdomen examinations. Hwang et al. (2021) and Almén et al. (2022) had lower DRLs compared to the DRL values in this study. The lower radiation dose could result from the positioning of the patient to the isocenter, the clinical indication diagnosed, or the protocol used for the CT abdominal examination. The CT unit used for the CT scans of participants involved in this study uses the ATCM, which was proved to reduce radiation dose when applied (ICRP, 2017:81). The CT abdomen scans used in this study were acquired with a single-phase scan. Single-phase scans result in a lower radiation dose than multi-phase scans (Zacharias et al., 2013:951). In the study of Hwang et al. (2021), they also reported using ATCM and IR algorithms for paediatric CT examinations. As in this study, Hwang et al. (2021) acquired CT abdominal examinations with a single-phase scan with contrast medium. Therefore, these factors, such as the use of ATCM, contrast medium, and the number of scan phases, should be considered when comparing paediatric DRL values developed in this study, with other paediatric DRL values.

4.4 CONCLUSION

This study proposes paediatric LDRL values for contrast-enhanced abdominal CT examinations to investigate and stage nephroblastoma cases. The paediatric LDRL values were developed for age, weight, and effective diameter groups. Based on the findings, weight and effective diameter, impacted the patient's dose and most reliable categorising groups. The patient's effective diameter closely correlates with weight and considers a specific portion of the anatomy being imaged. Thus, the effective diameter can be used as an additional tool for weight categorisation to establish DRL values. The paediatric LDRL values developed in this study were also compared with DRL values developed in international studies. The paediatric DRL values developed in the latter studies were lower than most DRL values developed in other studies. Therefore, paediatric LDRL values developed in this study can be used as reference levels for a low-dose protocol for paediatric patients and should be used as a reference for radiation administration for nephroblastoma patients. As a result of this study, LDRL values have been established which can hopefully be used by clinicians to optimize the radiation dose delivered to paediatric nephroblastoma patients. LDRL values developed in this study will be used as a reference/baseline to indicate high unusual doses in paediatric who present with nephroblastoma for CT abdomen. Additionally, these methods will be presented to the participating imaging departments so that they can assist the medical physicist in developing DRL values.

Chapter 5, entitled **Conclusion, recommendations and limitations**, will outline and summarise the study's main findings, including the study overview, conclusion, limitations and recommendations.

CHAPTER 5: CONCLUSION, RECOMMENDATIONS AND LIMITATIONS

5.1 INTRODUCTION

The aim of this study was to establish paediatric LDRL values for contrast-enhanced abdominal CT examinations for the clinical indication of nephroblastoma based on the size of the patient. The DRL values are recommended levels by international guidelines (ICRP 2017:45) and EC (2018:14) that imaging facilities should use to evaluate their methods and determine if acceptable image quality can be achieved at lower dose levels (Habib Geryes et al., 2019:19). This study provides DRL values for nephroblastoma patients and will serve as a guide for optimising radiation dose for CT abdomen in paediatric patients. In this chapter, an overview of the study, followed by a discussion of the conclusion, limitations, and recommendations, will be provided. The study overview answers the research question and summarises the objectives achieved through this study. The conclusion of the study outlines the key points and states the value and significance of this study. The limitation section discusses the weaknesses of the study because of factors that could not be controlled. The recommendations in this research study are suggestions that should be considered when addressing the study's limitations based on the study results.

5.2 OVERVIEW OF THE RESEARCH STUDY

The aim of the study was to establish paediatric LDRL values for contrast-enhanced abdominal CT examinations to investigate and stage nephroblastoma cases. In section 5.2.1, the research question and objectives that were pursued to achieve the overall goal of the study will be discussed.

5.2.1 Research question and objectives

The research question that addressed the problem statement of this study was:

What are the paediatric LDRL values for contrast-enhanced abdominal CT examinations for nephroblastoma cases to ensure diagnostic images and optimised radiation usage?

The paediatric LDRL values were developed in this study for contrast-enhanced abdominal CT examinations for nephroblastoma (see Table 4.18) using a structured data recording document.

The following study objectives were pursued to achieve the aim of this study:

- Objective 1 was to develop paediatric LDRL values that are linked to the patient's weight and age for contrast-enhanced abdominal CT examination for nephroblastoma cases. The paediatric LDRL values that are linked to the patient's weight and age for contrast-enhanced abdominal CT examination for nephroblastoma cases were developed in this study and are indicated in Table 4.18 (see Chapter 4). This objective also indicates the difference between the influence of age and weight on paediatric patients to further support the suggestion made by ICRP (2017:97) that weight should be used for categories instead of age.
- Objective 2 was to compare LDRL values calculated using weight versus the effective diameter of the patient. Table 4.14 (see Chapter 4) indicates the comparison of the LDRL values calculated using weight versus the effective diameter of the patient. The weight and effective diameter LDRL values were comparable, and Spearman's coefficient correlation indicated a significant correlation between patient weight and effective diameter. This strong correlation was also noted in the studies conducted by Hwang et al. (2021:1177) and Imai et al. (2015:351). However, the ICRP (2017:97) recommended that effective diameter should be considered, in addition to weight, during the development of DRL values.
- Objective 3 was to compare the clinical indication-based LDRL values with other internationally published clinical indication-based LDRL values. This study's clinical indication-based LDRL values were also compared with the internationally published LDRL values, as seen in Table 4.18 of Chapter 4. No studies could be found in South Africa or internationally that have developed LDRL values specifically for nephroblastoma in paediatric patients. One study

found was Almén et al. (2022:5), in which paediatric DRL values for CT abdomen were developed by grouping patients based on their weight and age. However, the clinical indication discussed by Almén et al. (2022:5), did not include nephroblastoma. Other studies, such as that of Strauss et al. (2017), Muhammad et al. (2020), Van der Merwe and Mahomed (2020) and Hwang et al. (2021), used the same grouping method suggested by the ICRP (2017:93), but their studies did not include nephroblastoma of paediatric patients. The studies of Hwang et al. (2021), Satharasinghe et al. (2022) and Imai et al. (2015) used the SSDE dose quantity but did not develop paediatric DRL values for nephroblastoma. Thus, the paediatric LDRL values developed in this study could not be directly compared to any study.

5.3 CONCLUSION

In this study, paediatric LDRL values for contrast-enhanced abdominal CT examinations were developed to investigate and stage nephroblastoma in paediatric patients. Based on the findings of this study through a literature search, there are no paediatric DRL values for abdominal CT examinations developed for nephroblastoma in South Africa or internationally. Therefore, to the best of the researcher's knowledge, this is the first study that has developed size-specific LDRL values based on nephroblastoma for paediatric patients.

In this study, paediatric LDRL values were established based on nephroblastoma using three grouping methods, namely age groups, weight groups and effective diameter groups. A study conducted by Almén et al. (2022) was the only study where paediatric DRL values were developed for CT abdomen based on tumour and infection; the type of tumour or infection was not specified in that study. Almén et al. (2022:2) used age and weight groups to develop paediatric DRL values, but SSDE was not used as a dose quantity in their study. The paediatric CT abdominal examination in the Almén et al. (2022) study was acquired with one scan sequence with no contrast, which is different from this study, where contrast medium was used in all CT abdominal examinations. The study of Almén et al. (2022) did not mention the use of ATCM or IR algorithms on CT abdominal examinations; this explains the possible reason for the difference in the DRL values developed in this study, as all CT

abdominal examinations were acquired using ATCM and IR algorithms. The other main difference with this study is that Almén et al. (2022) did not develop paediatric DRL specifically for nephroblastoma patients. The SSDE dose quantity was used in the studies of Hwang et al. (2021), Satharasinghe et al. (2022) and Imai et al. (2015), but all these studies did not develop paediatric DRL values for nephroblastoma. The study of Hwang et al. (2021) and Imai et al. (2015) did not specify the SSDE dose quantity they used, while the study of Satharasinghe et al. (2022) focused on SSDE_{Effective Diameter} and SSDE_{Water Equivalent Diameter}. The paediatric LDRL values developed in this study could not be compared directly with the international DRL values developed for CT abdomen examinations. No studies have been found where paediatric LDRL values were developed for nephroblastoma, using age groups, weight groups, and effective diameter groups. Comparing this study with an international study was based on common factors, such as CT abdomen examinations and age/weight/effective diameter groups, similar to the ones used in this study.

The paediatric LDRL values developed in this study were slightly lower than most DRL values in various studies (Table 4.18 of Chapter 4). The radiation dose accumulated by paediatric patients involved in this study was lower due to the use of ATCM and IR algorithms. Hwang et al. (2021) also indicated that the ATCM and IR algorithms were used for CT examinations involved in their studies. The CT abdominal examination in the Hwang et al. (2021) study was acquired with a single-phase scan with contrast, similar to the CT abdominal examination in this study. The ATCM and IR were proved to be significantly lower the radiation dose, leading to lower paediatric LDRL values. Therefore, factors such as ATCM, IR and the number of scan sequences (protocol) should be considered when comparing the paediatric LDRL values developed in this study with those of other studies. This study's DRL values were higher compared to Hwang et al. (2021) and Almén et al. (2021),2022) due to different protocols and CT units. The South African Health Products Regulatory Authority (SAHPRA) (2022:15) suggested that the DRL values developed for the institution should not be exceeded when good and normal practice regarding diagnostic and technical performance is applied. Therefore, when good and normal practice regarding diagnostic and technical performance is applied, the paediatric LDRL values developed in this study should not be exceeded. As the ICRP (2017:31) and the SAHPRA (2022:15) suggested, the DRL

values should be used as a basis for comparison and not as an exposure limit. The LDRL values developed in this study can be used as a reference/baseline for the participating hospital when developing future paediatric DRL values for CT abdomen based on nephroblastoma.

The paediatric LDRL values calculated using weight were compared with paediatric LDRL values calculated using effective diameter to determine which variable is reliable for setting paediatric LDRL values. Both the variables were strongly correlated to each other; however, the effective diameter should be used as an additional method, as suggested by ICRP (2017:97). The results of this study indicated that effective diameter groups are the most reliable categories for grouping paediatric patients when developing paediatric LDRL values. This is because the effective diameter represents dimensional measurement at a specific cross-sectional image, while weight and age do not represent the portion of the anatomy being imaged (Cook et al., 2013:2). This is the same case with the use of SSDE as a dose quantity to develop DRL values. The SSDE dose quantity incorporates corrections based on the patient size, calculated from linear dimensions measured on the patient or a CT image of the patient (AAPM, 2011:18). Therefore, the effective diameter groups with the weight groups, should be used to categorise patients while the SSDE dose quantity should be used to develop paediatric DRL values. The clinical indication should also be considered when developing paediatric DRL values (see section 2.2.6). This is because different clinical indications of the same anatomical structure may require different exposures, examinations, or protocols (ICRP, 2017:32).

5.4 LIMITATIONS OF THE RESEARCH STUDY

The research study also had limitations:

1. First, the unavailability of the patient registers for patients who underwent CT abdomen before 2018 resulted in a small sample size. Thus, only data from 1 January 2018 to 31 December 2021 could be collected retrospectively.
2. Second, the minimum prescribed number of 20 to 30 patients for the age groups (group 1 [$<1M$] and group 5 [14y - $<18y$]), weight groups (group 1 [0kg – $<5kg$], group 4 [30kg – $<50kg$] and group 5 [50kg – $<80kg$]) and the effective diameter group 1 [$<13\text{ cm}$]; and the effective diameter group 4 [20 cm to $<24\text{ cm}$]) and

group 5 [>24 cm), to develop LDRL values for abdominal CT (nephroblastoma) examinations as recommended by the ICRP (2017:39), were not possible.

3. The third limitation was the lack of patients for the respective weight, age and effective diameter groups with fewer than 20 to 30 patients. This resulted in the inability to compile LDRL values for those of different ages, weights, and effective diameter groups for CT abdomen for nephroblastoma. Hwang et al. (2021:1183) and Almén et al. (2022:9) also had the same limitation, where they could not calculate paediatric DRL values for the different age and weight groups due to insufficient data.
4. The fourth limitation was that the patient's weight was not always directly measured. The researcher had to convert the volume of contrast medium injected to determine the patient's weight. Therefore, a slight difference could exist between the patient's actual weight and the converted weight.
5. Initially, it was planned to retrieve data from January 2016, but the CT department no longer had the patient register file for 2016 and 2017; thus, data was retrieved from 1 January 2018 to 31 December 2021.

5.5 CONTRIBUTION OF THE RESEARCH

The established LDRL values in this study will hopefully contribute as a guide to optimise the radiation dose received by paediatric patients for nephroblastoma. In addition, the methods that were used in this study will be presented to the participating imaging department so that radiographers can be equipped to assist the medical physicist in developing DRL values for the imaging department.

5.6 RECOMMENDATIONS

The following recommendations were devised by the researcher:

- I. To improve the accuracy of the results, the researcher recommends that the patient's weight should be recorded directly from the patient instead of calculating it from the contrast medium injected during the procedure.
- II. The effective diameter groups should be used to categorise patients when DRL values are established. Patient weight can be used as an alternative, as suggested by ICRP (2017:97), to categorise paediatric patients.

- III. The dose quantity, SSDE, should be used to develop paediatric DRL values since the SSDE is based on the size of the patient (AAPM, 2011:18).
- IV. Similar future studies should include enough patients per weight or effective diameter group (20 to 30 patients) to ensure all weight and effective diameter groups have LDRL values.
- V. To avoid a shortage of patients per weight group, imaging departments should consider recording each patient's weight using a standard operating procedure.
- VI. It is also important to consider the clinical indication when developing paediatric DRL values due to differences in CT protocols, and that exposure levels can differ for the same anatomical location.
- VII. Factors contributing to overall patient radiation (ATCM, IR algorithms and number of scan phases/protocol) should also be considered when developing paediatric DRL values.
- VIII. There is a need for national DRL values for nephroblastoma paediatric patients in South Africa because, as has been discussed earlier, nephroblastoma has been found to be the most common clinical indication in the participating hospital.

5.7 CONCLUSIVE REMARKS

A literature review found no documented paediatric LDRL values in South Africa or international studies for CT abdomen examination of nephroblastoma patients. Therefore, the aim of the study was to establish paediatric LDRL values for contrast-enhanced abdominal CT examinations, as well as to investigate and stage nephroblastoma cases. It is hoped that paediatric LDRL values developed in this study will be used as a tool to optimise abdominal CT examination for paediatric patients with nephroblastoma. As mentioned earlier, CT paediatric examinations should be justified and optimised to avoid high unnecessary radiation dose (Saravanakumar et al., 2016:342). The paediatric LDRL values for CT abdomen of patients with nephroblastoma were developed in this study using three grouping methods: age groups, weight groups, and effective diameter groups. The study by Almén et al. (2022) did not mention the use of ATCM or IR algorithms on CT abdominal examination. Based on the findings of this study, paediatric LDRL values are most reliable when grouped by weight and effective diameter. For paediatric DRL values, it

is therefore recommended that the categorisation method, the effective diameter groups used as an additional tool to weight groups and the dose quantity SSDE, be used. It is also important to consider the clinical indications when developing paediatric DRL values (see section 2.2.6). This is because the protocols and exposure levels for CT examinations performed at the same anatomical location may differ depending on the clinical indication. Thus, the paediatric LDRL values developed in this study can be used as a baseline for future paediatric DRL values for the CT abdomen of nephroblastoma patients.

REFERENCES

- Abdulkadir, M.K., Izge, I.Y., Yunusa, G.H., Mohammed, A. & Osman, N.D. (2021). Evaluation of age-based radiation dose in paediatric patients received from head CT examination at a tertiary hospital, Nigeria. *Radiation Physics and Chemistry*, 182, 109380.
- Aberle, C., Ryckx, N., Treier, R. & Schindera, S. (2019). Update of national diagnostic levels for adult CT in Switzerland and assessment of radiation dose reduction since 2010. *European Radiology*, 30(3), 1690–1700.
- Adegboyega, O.A., Osuji, R.I., Akinola, R.A., Balogun, B.O., Fatureti, I.O. & Awosanya, G.O. (2014). Pattern of computed tomography scan findings in children with Wilms' tumor in a tertiary hospital in Lagos, Nigeria. *Indian Journal of Medical and Paediatric Oncology*, 35(1), 31–35.
- Afzalipour, R., Abdollahi, H., Hajjalizadeh, M.S., Jafari, S. & Mahdavi, S.R. (2019). Estimation of diagnostic reference levels for children computed tomography: a study in Tehran, Iran. *International Journal of Radiation Research*, 17(3), 415–421.
- Almén, A., Guðjónsdóttir, J., Heimland, N., Højgaard, B., Waltenburg, H. & Widmark, A. (2022). Paediatric diagnostic reference levels for common radiological examination using the European guidelines. *The British Journal of Radiology*, 95(1130), 20210700.
- Almohiy, H. (2014). Paediatric computed tomography radiation dose: a review of the global dilemma. *World Journal of Radiology*, 6(1), 1–6.
- Alshowiman, S.S., Sahrah, A.H., Alswailem, A.K., Alotaibi, S.F., Altowaijiri, A.A. & Alghathami, W.A. (2021). Iodinated contrast media. *World Journal of Advanced Research and Reviews*, 9(1), 156–167.

Alsleem, H., Tajaldeem, A., Almutairi, A., Almohiy, H., Aldaais, E., Albattat, R., Alsleem, M., Abuelhia, E., Kheiralla, O.A., Alqahtani, A., Alghamdi, S., Aljondi, R. & Alharbi, R. (2022). The actual role of iterative reconstruction algorithm methods in several Saudi Hospitals as a tool for radiation dose minimization of Ct scan examinations. *Journal of Multidisciplinary Healthcare*, 15, 1747–1757.

American Association of Physicists in Medicine (AAPM). (2011). AAPM Report No. 204. Size-specific dose estimates (SSDE) in paediatric and adult body CT examinations. College Park, MD: AAPM. Available at: https://www.aapm.org/pubs/reports/rpt_204.pdf (accessed 31 August 2024).

American College of Radiology. (2021). ACR–SABI–SAR–SPR practice parameter for the performance of computed tomography (CT) of the abdomen and computed tomography (CT) of the pelvis. Practice parameter: CT abdomen CT pelvis, 1–15. Virginia, US: ACR. Available at: <https://www.acr.org/-/media/ACR/Files/Practice-Parameters/ct-abd-pel.pdf> (accessed 11 September 2024).

Bibbo, G., Brown, S. & Linke, R. (2016). Diagnostic reference levels of paediatric computed tomography examinations performed at a dedicated Australian paediatric hospital. *Journal of Medical Imaging and Radiation Oncology*, 60(4), 475–484.

Bolowia, N. (2018). Establishment of computer tomography diagnostic reference levels in Tobruk. *Journal of Medical Diagnostic Methods*, 7(3), 1000274.

Brady, Z., Ramanauskas, F., Cain, T.M. & Johnston, P.N. (2012). Assessment of paediatric CT dose indicators for the purpose of optimisation. *The British Journal of Radiology*, 85(1019), 1488–1498.

Bruesewitz, M.R., Yu, L., Vrieze, T.J., Kofler, J.M. & McCollough, C.H. (2008). Smart mA – Automatic Exposure Control (AEC): physics principles and practical hints. Presented at: Annual meeting of the Radiological Society of North America; 2008

Chen, J.H., Jin, E.H., He, W. & Zhao, L.Q. (2014). Combining automatic tube current modulation with adaptive statistical iterative reconstruction for low-dose chest CT screening. *PLoS ONE*, 9(4), e92414.

Choi, W., Lee, J.W., Huh, M-H. & K, S-H. (2003). An algorithm for computing the exact distribution of the Kruskal-Wallis test. *Communications in statistics*, 32(4): 1029-1040

Cook, T.S., Chadalavada, S.C. & Boom, W.W. (2013). How inaccurate is weight as a metric for patient size? Comparing patient weight to effective diameter for size-specific dose estimation. *Proceedings of the SPIE*, 8674(867408):1–6.

European Commission (EC). (2018). European guidelines on diagnostic reference levels for paediatric imaging. Radiation Protection N° 185. Luxembourg: European Union. Available at: <https://data.europa.eu/doi/10.2833/486256> (accessed 31 August 2024).

Feger, I., Campos, A. & Murphy, A. (2023). CT chest abdomen-pelvis (protocol). Reference article, Radiopaedia.org. Available at: <https://radiopaedia.org/articles/ct-chest-abdomen-pelvis-protocol-2> (accessed 31 August 2024).

Foster, T. (2023). Wilms tumor. Reference article, Radiopaedia.org. Available at: <https://radiopaedia.org/articles/wilms-tumour> (accessed 31 August 2024).

Government of Canada. (2024) Health effects of ionizing radiation on children. Available at: <https://www.cnsccsn.gc.ca/eng/resources/radiation/effects-of-radiation-on-children/> (accessed 22 January 2025).

Habib Geryes, B., Hornbeck, A., Jarrige, V., Pierrat, N., Ducou Le Pointe, H. & Dreuil, S. (2019). Patient dose evaluation in computed tomography: a French nation study based on clinical indications. *Physica Medica*, 61, 18–27.

Hernández, L., Terradas, M., Camps, J., Martín, M., Tusell, L. & Genescà, A. (2015). Aging and radiation: bad companions. *Aging Cell*, 14(2), 153–161.

Hojreh, A., Weber, M. & Homolka, P. (2015). Effect of staff training on radiation dose in pediatric CT. *European Journal of Radiology*, 84(8), 1574–1578.

Hwang, J.Y., Choi, Y.H., Yoon, H.M., Ryu, Y.J., Shin, H.J., Kim, H.G., Lee, S.M., You, S.K. & Park, J.E. (2021). Establishment of local diagnostic reference levels of pediatric abdominopelvic and chest CT examinations based on the body weight and size in Korea. *Korean Journal of Radiology*, 22(7), 1172-1184

Imai, R., Miyazaki, O., Horiuchi, T., Kurosawa, H. and & Nosaka, S. (2015). Local diagnostic reference level based on size-specific dose estimates: assessment of pediatric abdominal/pelvic computed tomography at a Japanese national children's hospital. *Pediatric Radiology*, 45(3), 345–353.

Inoue, Y., Itoh, H., Nagahara, K., Hata, H. & Mitsui, K. (2023). Relationships of radiation dose Indices with body size Indices in adult body computed tomography. *Tomography*, 9(4), 1381–1392.

International Commission on Radiological Protection (ICRP). (2007). ICRP Publication 103. The 2007 Recommendations of the International Commission on Radiological Protection. *Annals of the ICRP*, 37(2-4):1–339.

International Commission on Radiological Protection (ICRP). (2017). ICRP Publication 135. Diagnostic reference levels in medical imaging. *Annals of the ICRP*, 46(1): 1–144.

Järvinen, H., Seuri, R., Kortensniemi, M., Lanjunen, A., Hallinen, E., Savikurki-Heikkilä, P., Laarne, P., Perhomaa, M. & Tyrväinen, E. (2015). Indication-based national diagnostic reference levels for paediatric CT: a new approach with proposed values. *Radiation Protection Dosimetry*, 165(1–4), 86–90.

Kessler, R., Hegenscheid, K., Fleck, S., Khaw, A., Kirsch, M., Hosten, N. & Langner, S. (2014). Patient body weight-tailored contrast medium injection protocol for the craniocervical vessels: a prospective computed tomography study. *PLoS ONE*, 9(2), e88867.

Khan, A.N. (2023). Wilms tumor imaging. Available at: <https://emedicine.medscape.com/article/415012-overview?form=fpf> (accessed 31 August 2024).

Kivunja, C. (2018). Distinguishing between theory, theoretical framework, and conceptual framework: a systematic review of lessons from the field. *International Journal of Higher Education*, 7(6), 44–53.

Kozłowski, F.M., van Reenen, C.J. & Trauernicht, C.J. (2024). Establishment of local diagnostic reference levels for CT colonography at a tertiary hospital. *SA Journal of Radiography*, 28(1), 2809.

Lander, A. & Newman, J. (2013). Paediatric anatomy. *Surgery*, 31(3), 101–105.

Lampignano, J.P. & Kendrick, E.L. (2014). *Textbook of Radiographic Positioning and Related Anatomy*. 8th edition. St. Louis, MO: Elsevier, 59.

Lee, K.L., Beveridge, T., Sanagou, M. & Thomas, P. (2019). Updated Australian diagnostic reference levels for adult CT. *Journal of Medical Radiation Sciences*, 67(1), 5–15.

Lesetja, K. (2021) Conversation with Tebello Pitso, 01 February.

Maxfield, M.W., Schuster, K.M., McGillicuddy, E.A., Young, C.J., Ghita, M., Bokhari, S.A., Oliva, I.B., Brink, J.A. & Davis, K.A. (2012). Impact of adaptive statistical iterative reconstruction on radiation dose in evaluation of trauma patients. *The Journal of Trauma and Acute Care Surgery*, 73(6), 1406–1411.

McCombes, S. (2019). Descriptive research. Definition, types, methods & examples. Available at: <https://www.scribbr.com/methodology/descriptive-research/> (accessed 31 August 2024).

Microsoft Corporation. (2015). *BitLocker encryption of Windows 10*. Redmond, WA 98052-6399, USA

Middleton, F. (2019). The 4 types of validity in research. Definitions & examples. Available at: <https://www.scribbr.com/methodology/types-of-validity/> (accessed 31 August 2024).

Mohammadbeigi, A., Khoshgard, K., Harhparast, A. and Eivazi, M.T. 2019. Local DRLs for paediatric CT examinations based on size-specific dose estimates in Kermanshah, Iran. *Radiation Protection Dosimetry*, (2019): 1-11.

Muhammad, N.A., Abdul Karim, M.K., Abu Hassan, H., Ahmad Kamarudin, M., Ding Wong, J.H. & Ng, K.H. (2020). Diagnostic reference level of radiation dose and image quality among paediatric CT examination in a tertiary hospital in Malaysia. *Diagnostics*, 10(8), 591.

National Institute of Biomedical Imaging and Bioengineering. (2022). Computed Tomography (CT). Bethesda, MD: NIBIB. Available at: <https://www.nibib.nih.gov/science-education/science-topics/computed-tomography-ct> (accessed 31 August 2024).

Nyathi, M. & Shivambu, I.S. (2019). Local diagnostic reference levels for common computed tomography procedures at a tertiary hospital in South Africa. *Iranian Journal of Medical Physics*, 16(5), 349–354.

Ogbole, G.I. (2010). Radiation dose in paediatric computed tomography: risks and benefits. *Annals of Ibadan Postgraduate Medicine*, 8(2), 118–126.

Otto, J.H., Janse Van Rensburg, J. & Stones, D.K. (2015). Post-treatment surveillance abdominopelvic computed tomography in children with Wilms tumour: is it worth the risk? *SA Journal of Radiology*, 19(1), 784.

Papadakis, A.E. & Damilakis, J. (2019). Automatic tube current modulation and tube voltage selection in pediatric computed tomography: a phantom study on radiation dose and image quality. *Investigative Radiology*, 54(5), 265–272.

Parsi, M., Sohrabi, M., Mianji, F. & Paydar, R. (2018). Determination of examination-specific diagnostic reference level in computed tomography by a new quality control-based dose survey method. *Health Physics*, 114(3), 273–281.

Paulo, G., Damilakis, J., Tsapaki, V., Schegerer, A.A., Repussard, J., Jaschke, W., Frija, G. & European Society of Radiology. (2020). Diagnostic reference levels based on clinical indications in computed tomography: a literature review. *Insights Into Imaging*, 11(1), 96.

Poole, J.E. (2010). Wilms' tumour (nephroblastoma). *Continuing Medical Education*, 28(7), 324–326.

Public Health England. (2014). *Doses from Computed Tomography (CT) Examinations in the UK – 2011 Review*. Oxfordshire, UK: Crown. Available at: <https://www.biophysicssite.com/CTSurvey/PHE-CRCE-013.pdf> (accessed 31 August 2024).

Raman, S.P., Mahesh, M., Blasko, R.V. & Fishman, E.K. (2013). CT scan parameters and radiation dose: practical advice for radiologists. *Journal of the American College of Radiology*, 10(11), 840–846.

Rawashdeh, M., Saade, C., Al Mousa, D.S., Abdelrahman, M., Kumar, P. & McEntee, M. (2023). A new approach to dose reference levels in pediatric CT: age and size-specific dose estimation. *Radiation Physics and Chemistry*, 205, 110698.

Saravanakumar, A., Vaideki, K., Govindarajan, K.N., Devanand, B., Jayakumar, S. & Sharma, S.D. (2016). Establishment of CT diagnostic reference levels in select procedures in South India. *International Journal of Radiation Research*, 14(4), 341–347.

Satharasinghe, D., Jeyasugiththan, J., Wanninayake, W.M., Pallewatte, A.S. & Samarasinghe, R.A. (2022). Patient size as a parameter for determining diagnostic reference levels for paediatric computed tomography (CT) procedures. *Physica Medica*, 102, 55–65.

Sawyer, S.F. (2009). Analysis of variance: the fundamental concepts. *Journal of Manual & Manipulative Therapy*, 17(2), E27–E38.

SPC radiology. Tricky terms explained: Non-contrast vs contrast CT scan. Available at: <https://www.scp.co.za/radiology-explained/non-contrast-vs-contrast-ct-scan-whats-the-difference/#:~:text=A%20contrast%2Denhanced%20CT%20scan,their%20visibility%20on%20the%20images> (accessed 04 February 2025).

Şener, U., Tellioğlu, A.M. & Polat, Y.D. (2022). A reappraisal of pediatric abdominal surface anatomy. *Clinical Anatomy*, 35(1), 103–115.

Shibata, S., Shibamoto, Y., Maehara, M., Hobo, A., Hotta, N. & Ozawa, Y. (2020). Reasons for undergoing CT during childhood: can CT-exposed and CT-naïve populations be compared? *Dose Response*, 18(1): 1559325820907011.

Sohn, S. & Liu, H. (2014). Analysis of medication and indication occurrences in clinical notes. *AMIA Annual Symposium Proceedings*, 2014, 1046–1055

South African Health Products Regulatory Authority (SAHPRA). (2022). Guideline for code of practice for users of medical x-ray equipment. SAHPGL-RDN-XR-02_v1. Pretoria: SAHPRA. Available at: <https://www.sahpra.org.za/document/guideline-for-code-of-practice-for-users-of-medical-xray-equipment/> (accessed 31 August 2024).

Strauss, K.J., Goske, M.J., Towbin, A.J., Sengupta, D., Callahan, M.J., Darge, K., Podberesky, D.J., Frush, D.P., Maxfield, C., Westra, S.J., Prince, J.S., Wu, H. & Bhargavan-Chatfield, M. (2017). Pediatric chest CT diagnostic reference ranges: development and application. *Radiology*, 284(1), 219–227.

Stumpfegger, E. (2017). Trustworthiness of research. Available at: <https://www.munich-business-school.de/insights/en/2017/trustworthiness-of-research/> (accessed 31 August 2024).

Subramaniam, H., Taghavi, K. & Mirjalili, S.A. (2016). A reappraisal of pediatric abdominal surface anatomy utilizing in vivo cross-sectional imaging. *Clinical Anatomy*, 29(2), 197–203.

Swaen, B. & George, T. (2024). What Is a Conceptual Framework? | Tips & Examples. Available at: <https://www.scribbr.com/methodology/conceptual-framework/#:~:text=A%20conceptual%20framework%20is%20a,existing%20studies%20about%20your%20topic>. (accessed 22 January 2025)

Taherdoost, H. (2016). Sampling methods in research methodology; how to choose a sampling technique for research. *International Journal of Academic Research in Management*, 5(2), 18–27.

Tsapaki, V., Damilakis, J., Paulo, G., Schegerer, A.A., Repussard, J., Jaschke, W. & Frija, G. (2021). CT diagnostic reference levels based on clinical indications: results of a large-scale European survey. *European Radiology*, 31(7): 4459–4469.

Van der Merwe, C.M. & Mahomed, N. (2020). An audit of radiation doses received by paediatric patients undergoing computed tomography investigations at academic hospitals in South Africa. *SA Journal of Radiology*, 24(1), 1823.

Varan, A. (2008). Wilms' tumor in children: an overview. *Nephron Clinical Practice*, 108(2), c83–c90.

Vawda, Z. (2017). Diagnostic reference levels for paediatric computed tomography. *SA Journal of Radiography*, 21(1), a1152.

Watson, R. (2015). Quantitative research. *Nursing Standard*, 29(31), 44–48.

Yiallourous, M. (2017). Wilms tumour (nephroblastoma) – brief information. Available at:

https://www.gpoh.de/kinderkrebsinfo/content/diseases/solid_tumours/wilms_tumour_nephroblastoma/pohwilms_patinfokurz120120611/index_eng.html (accessed 31 August 2024).

Zacharias, C., Alessio, A.M., Otto, R.K., Iyer, R.S., Philips, G.S., Swanson, J.O. & Thapa, M.M. (2013). Pediatric CT: strategies to lower radiation dose. *American Journal of Roentgenology*, 200(5), 950–956.

Zira, D.J., Yahaya, T.H., Umar, M.S., Nkubli, F.B., Chukwuemeka, N.C., Sidi, M., Emmanuel, R., Ibrahim, F.Z., Laushugno, S.S. & Ogenyi, A.P. (2021). Clinical indication-based diagnostic reference levels for paediatric head computed tomography examination in Kano Metropolis, Northwestern Nigeria. *Radiography*, 27(2), 617–621.

APPENDICES

APPENDIX A- DATA RECORDING DOCUMENT

Unique number

Data recording document of CT doses				
Name of machine: General Electric (GE) Healthcare			Model of machine: Discovery 750 HD	
Number of detector rows: 64				
Patient examination number: UM _____		Age: _____ Weight: _____ kg	Gender: Male ☐ Female ☐	
CT examination: Chest ☐ Abdomen ☐ Chest-abdomen-pelvis ☐		Clinical indication: Nephrosarcoma ☐		
CT protocol: _____				
Parameters	Sequence 1	Sequence 2	Sequence 3	Sequence 4
CTDI _{vol} (mGy):				
Total CTDI_{vol} (mGy): _____				
DLP (mGy.cm):				
Total DLP (mGy.cm): _____				
The volume of IV contrast used:				
AP Dimension in cm: _____				
LAT Dimension in cm: _____				
Sum of AP and LAT Dimension in cm: _____				
Effective diameter (D_{eff}):				

APPENDIX B- ETHICAL APPROVAL OBTAINED FROM HSREC

UNIVERSITY OF THE
FREE STATE
UNIVERSITEIT VAN DIE
VRYSTAAT
YUNIBESITHI YA
FRIDISTATA



UFS·UV
HEALTH SCIENCES
GESONDHEIDSWETENSKAPPE

Health Sciences Research Ethics Committee

29-Nov-2023

Dear **Tebello Pitso**

Ethics Number: UFS-HSD2022/0341/0008-0003

Ethics Clearance: **LOCAL DIAGNOSTIC REFERENCE LEVELS (LDRLs) FOR PAEDIATRIC CONTRASTED ABDOMINAL COMPUTED TOMOGRAPHY (CT) EXAMINATIONS FOR NEPHROBLASTOMA.**

Principal Investigator: **Tebello Pitso**

Department: **CUT - Central University of Technology**

[Submission Page](#)

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:

- Annual re-approval: The ethical clearance of this project is extended to 27 November 2024.

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(2020); 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; International Council for Harmonisation (ICH) Harmonised Guideline, Integrated Addendum to ICH E6(R1), Guideline for Good Clinical Practice (GCP) E6(R2), 2016; SAHPRA Guidelines as well as Laws and Regulations with regard to the Control of Medicines, Constitution of the HSREC of the Faculty of Health Sciences.

The Principal Investigator (PI) bears final responsibility for the RIMS application. In the event of any misconduct or improper activities perpetrated by a third party, the PI will be held vicariously liable. The HSREC will bear no responsibility or liability for any actions of a PI and/or third party or breach of confidentiality caused by the PI and/or third party.

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



Prof. A. Sherriff

Chairperson : Health Sciences Research Ethics Committee

Health Sciences Research Ethics Committee

Office of the Dean: Health Sciences

T: +27 (0)51 401 2352/9860 | E: ethicsfhs@ufs.ac.za

IRB 00017962; REC 230408-011; ICROD 001009; FWA 00027947

Block D, Dean's Devices, Room D104 | P.O. Box 339 (Internal Post Box 040) | Bloemfontein 9300 | South Africa

www.ufs.ac.za



APPENDIX C- APPROVAL LETTER- FREE STATE DEPARTMENT OF HEALTH



health

Department of
Health
FREE STATE PROVINCE

05 August 2022

Mr Tebello Pitso
CUT- Central University of Technology

Dear Mr. T Pitso

Subject: Local Diagnostic Reference Levels (DRLs) for Paediatric Contrast Abdominal Computed Tomography (CT) Examinations for Nephroblastoma.

- Please ensure that you read the whole document, Permission is hereby granted for the above – mentioned research on the following conditions:
- Participation in the study must be voluntary
- A written consent by each participant must be obtained.
- Serious adverse events to be reported to the Free State department of health and/ or termination of the study
- Ascertain that your data collection exercise neither interferes with the day-to-day running of Universitas Hospital nor the performance of duties by the respondents or health care workers.
- The DOH expects that the researcher will be the responsible data manager according to the POPI Act. The responsibility thus lies with the researcher to ensure that the processing of all participant's personal information and research data is lawful according to the stipulations of the POPI Act (Protection of Personal Information Act 4 of 2013).
- Confidentiality of information will be ensured and please do not obtain information regarding the identity of the participants.
- Department of Health to be fully indemnified from any contravention of the POPI Act as you conduct this study.
- Research results and a complete report should be made available to the Free State Department of Health on completion of the study (a hard copy plus a soft copy).
- Progress report must be presented not later than one year after approval of the project to the Ethics Committee of the University of Free State and to Free State Department of Health.
- Any amendments, extension or other modifications to the protocol or investigators must be submitted to the Ethics Committee of the University of Free State and to Free State Department of Health.
- Conditions stated in your Ethical Approval letter should be adhered to and a final copy of the Ethics Clearance Certificate should be submitted to Sebeelats@fshealth.gov.za / Gwantshuwa@fshealth.gov.za before you commence with the study
- No financial liability will be placed on the Free State Department of Health
- Please discuss your study with Institution Manager on commencement for logistical arrangements.
- Department of Health to be fully indemnified from any harm that participants and staff experiences in the study
- As part of feedback you will be required to present your study findings/results at the Free State Provincial health research day

Trust you find the above in order.

Kind Regards



MNC-MNG MAHLATSI
HEAD: HEALTH

Date: 11/08/2022

Head: Free State Department of Health
PO Box 227, Bloemfontein, 9300
4th Floor, Executive Suite, Sephele House, on Matsieng and, Harway Road, Bloemfontein
Tel: (051) 406 1645 Fax: (051) 406 1556 e-mail: head@fshealth.gov.za / chiefexecutive@fshealth.gov.za

www.fs.gov.za

APPENDIX D- PERMISSION LETTER FROM THE IMAGING DEPARTMENT

Central University of Technology
1 President Brand Street
Bloemfontein
9301
21 June 2021

Head of Department

[REDACTED]
[REDACTED]

Bloemfontein
9301

To: Professor J Janse van Rensburg

REQUESTING PERMISSION TO ACQUIRE RESEARCH DATA

I, Tebello Pitso, request permission to collect data for research at the Clinical Imaging Sciences department of [REDACTED]. I am registered at the Central University of Technology for the Master of Radiography degree in Diagnostics. My main research project requires me to research a topic that addresses a gap in the literature. The topic that I have chosen is "Local diagnostic reference levels (DRLs) for paediatric contrasted abdominal computed tomography (CT) examinations for nephroblastoma".

The aim of the study is to establish paediatric local diagnostic reference level (LDRL) values for contrast abdominal computed tomography (CT) examinations at and to compare the output levels with published data. To achieve the aim, the following objectives of the study will be pursued:

- To develop paediatric LDRL values that are linked to the patient weight and age for contrasted abdominal CT examination based on nephroblastoma.
- To compare LDRLs calculated using weight versus effective diameter of the patient.

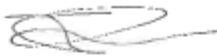
- To compare the clinical indication based LDRL values with other internationally published clinical indication based LDRL values.

I need your permission to access the CT patient request forms, CT patient register file and CT computer/ picture archiving and communication system (PACS) to obtain digital imaging and communications in medicine (DICOM) information for this study. The research protocol will be submitted to the University of the Free State Health Sciences Research Ethics Committee (HSREC) and the Free State Department of Health. I am willing to perform the data acquisition at an opportune time provided by the CT radiographers.

You are welcome to contact one of my supervisors or me should you require additional information on the study. Please e-mail the letter with the outcome of your decision on granting permission to perform research to the researcher at pitso.tebello1997@gmail.com.

Thank you in advance for your time. I hope to hear from you soon relating to this matter.

Yours faithfully,



Signature
Tebello Pitso

Date

Mrs. I-K Sebelego
Supervisor, Departmental of Clinical Sciences
Cell: 076 5888 029, E-mail: isebelego@cut.ac.za

Mrs. Henra Muller
Co-supervisor, Departmental of Clinical Sciences
Cell: 084 5060 004, E-mail: henramuller@cut.ac.za



Signature: Prof J Janse van Rensburg (HOD) Date

Prof J Janse van Rensburg
MMed(Rad.D)(Stell) PhD(UFS)
HOD Diagnostic Radiology
Department Clinical Imaging Sciences
Faculty of Health Sciences
University of the Free State
South Africa
jansevrj@ufs.ac.za
051 405 3471

APPENDIX E- LETTER FROM BIOSTATISTICIAN

Maryn Viljoen
Statistics Consulting Services

082 823 5731
maryn.viljoen1@gmail.com

Protocol & research methodology consultation | Ethical consultation | Database construction & capturing of data
Analysing data using statistical software packages (SAS Version 9.2) | Statistics consultation services to analyse and interpret data
Conveys results with statistical tables & 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

8 March 2022

Title: "LOCAL DIAGNOSTIC REFERENCE LEVELS (DRLs) FOR PAEDIATRIC
CONTRASTED ABDOMINAL COMPUTED TOMOGRAPHY (CT)
EXAMINATIONS FOR NEPHROBLASTOMA."

Researcher: Tebello Pitso (217008446)
Faculty of Health and Environmental Sciences
Department of Clinical Science: Programme Radiography
Central University of Technology, Free State
Bloemfontein

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
M.Sc. Risk Analysis (UFS)
maryn.viljoen1@gmail.com
082 82 35 731

APPENDIX F- LETTER FROM LANGUAGE EDITOR

DECLARATION OF LANGUAGE EDITING

Stirling Lodge
17 Epsom Rd.
Stirling 5401
East London
South Africa

03 September 2024

TO WHOM IT MAY CONCERN

This is to state that the Master's degree (MRAD): 'Local diagnostic reference levels (DRLs) for paediatric contrasted abdominal...' (text only), submitted to me by Mr T. Pitso (student number: 217008446) of the Central University of Technology, Free State, South Africa, has been language edited by me, according to the tenets of academic discourse.

Mrs Carol Julia Keep

MA (English); BEd (Hons.); SOD; Cert. of Proofreading

072 508 0936

caroljkeep@gmail.com



C J Keep

DECLARATION OF REFERENCE EDITING

Author: Mr Tebello Pitso

Title: LOCAL DIAGNOSTIC REFERENCE LEVELS (DRLs) FOR PAEDIATRIC CONTRASTED ABDOMINAL COMPUTED TOMOGRAPHY (CT) EXAMINATIONS FOR NEPHROBLASTOMA

TO WHOM IT MAY CONCERN

I, Theanette Mulder, hereby declare that I cross-checked the in-text references with the references in the bibliography and formatted all references to meet the selected reference style.

Important notice: The verification of the accuracy of citations in the list of references (authors and title of the article, journal name, date, volume, issue and page numbers, and DOI; or similar information and the URL for internet references; or textbooks used as references) does not include authentication of the content that was cited from the reference.



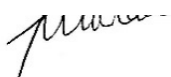
MS. THEANETTE MULDER

BSc, BSc (Hons)

Telephone: +27 (0)83 748 1455

Email address: theanette.med75@gmail.com

Date: 11 September 2024



MS. THEANETTE MULDER

BSc, BSc (Hons)

Telephone: +27 (0)83 748 1455

Email address: theanette.med75@gmail.com

Date: 11 September 2024

APPENDIX G- TURNITIN REPORT

LDRLs FOR PAEDIATRIC CONTRASTED ABDOMINAL CT EXAMINATIONS FOR NEPHROBLASTOMA

ORIGINALITY REPORT

5%

SIMILARITY INDEX

3%

INTERNET SOURCES

6%

PUBLICATIONS

0%

STUDENT PAPERS
