A radiation dose review for paediatric fluoroscopy in an Academic South African referral hospital

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A research report submitted to the Faculty of Health Sciences, University of the of Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree of Master of Medicine in Diagnostic Radiology.

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Declaration

I, Mauritz Venter, declare that this research report is my own work. It is being submitted for the degree of MMed (RadD) at the University of Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

DR MAURITZ VENTER

This 29th day of October 2018.

I dedicate this to Marli.

Thank you for your constant love and support.

Publications and presentations

The pilot study was presented at Euro- safe's paediatric imaging's workshop in Lisbon Portugal on 16 October 2015.

The abstract of this work was presented as a poster presentation at the 2nd RSSA SASPI congress in Stellenbosch South Africa on 4 November 2016.

The abstract of this work was published in the South African Journal of Radiology, Vol 21, No 1 (2017).

Abstract

INTRODUCTION

Children are more sensitive to radiation and it is therefore important to reduce their exposure. There are currently no published data on South African paediatric fluoroscopic upper GIT, contrasted enemas and vesico-urethrogram dosage reference levels.

AIM

To determine the dose area product (DAP) values in common paediatric fluoroscopic examinations: Upper GIT studies, contrasted enemas and vesico-urethrograms. The primary endpoint was comparing our median and upper third quartile DAP values to international standards.

METHOD

We adhere to the Radiological Society of South Africa (RSSA)/South African Society of Paediatric Imaging's (SASPI) guidelines to minimise radiation exposure. The upper third quartile and mean DAP values were collected between March 2013 and March 2016 for each study, categorised into four age groups (0–1, 2–5, 6–10 and 11–15 years) and stratified by our three major examinations. The data were compared to literature from the National UK Radiological Protection Board.

RESULTS

DAP values for upper GIT studies were significantly lower in the three younger age groups. There was no significant difference in the oldest age group. DAP values for vesico-urethrograms were significantly lower in the youngest age group. There was no significant difference in the three older age groups. For our contrasted enemas, there were no suitable data for comparison.

CONCLUSION

By following the RSSA / SASPI guidelines, our overall DAP values compared better than the UK National Patient Dose Database in the younger age groups and no worse in the older age groups.

Acknowledgements

It is with delight that I acknowledge the following individuals whose support, assistance and encouragement made this venture possible.

- My supervisor, Dr Jaishree Naidoo for providing me with the idea for the project, invaluable expertise as a paediatric radiologist and assistance with every aspect of the project every step of the way.
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- My wife, Marli for her love and constant support throughout this project.
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List of Abbreviations and Terminology

ALARA	As low as reasonably achievable
AML	Acute myeloid leukaemia
BEIR	Biological Effects of Ionising Radiation
cm^2	Centimetre squared
CML	Chronic myeloid leukaemia
CMJAH	Charlotte Maxeke Johannesburg Academic Hospital
CT	Computed Tomography
DAP	Dose- area Product
DNA	Deoxyribonucleic Acid
DRLs	Dosage Reference Levels
GIT	Gastrointestinal
Gy	Gray
$Gy.cm^2$	Gray times (x) centimetre squared
HPA	Health Protection Agency
ICRP	International Commission on Radiological Protection
KAP	Kerma- area product
kVp	Peak Kilovoltage
mAs	Milliamperage-seconds
MRI	Magnetic Resonance Imaging
msec	milliseconds
mSV	Milli Sievert
NCRP	National Council of Radiation Protection and Measurements
RSSA	Radiological Society of South Africa
SASPI	South African Society of Paediatric Imaging
UK	United Kingdom
VCU	Vesico-urethrogram

1. Introduction

Paediatric fluoroscopy is a commonly utilised special investigation to aid medical professionals in diagnosing and treating their patients. Fluoroscopic studies form part of the daily practice in numerous radiological departments all over the world (1). As with the other imaging modalities, such as ultrasonography, computed tomography (CT) and magnetic resonance imaging (MRI), fluoroscopy has been used with ever growing importance and popularity for the diagnoses and treatment of both medical and surgical conditions in children (2).

Paediatric fluoroscopy is routinely indicated in the work up for congenital anomalies of the upper and lower gastrointestinal track. The upper gastrointestinal (upper GIT) study is performed for proximal pathology and the contrasted enema for distal pathology. Both potentially life-threating conditions such as midgut malrotation and less emergent conditions, including Hirschsprung's disease, are ultimately diagnosed with fluoroscopy (3). The vesico-urethrogram (VCU) still plays an important role in modern medical imaging in the workup and monitoring diseases of the renal tract (4).

Apart from the indispensable diagnostic role that fluoroscopy plays, it also serves as a crucial tool in the actual management of childhood diseases. Interventional radiology spans over most major disciplines and includes several cardiac and non-cardiac procedures ranging from image guided tissue biopsies to embolization of neoplasms (5).

Unfortunately, the trade-off is that these procedures cause ionising radiation to the patient being examined with an increased risk of developing a malignancy. The progressive use of ionising radiation in paediatric imaging is of special concern because children's tissues are more sensitive to radiation, they have a larger cumulative lifetime radiation dose and on average have a longer lifetime in which potential deleterious effects can become evident. Children are consequently significantly more susceptible to radiation effects relative to adults (6).

1.1. Radiation Risk

Approximately fifty percent of radiation humans are subjected to is background radiation. This natural source consists largely of radioactive elements in the ground, while cosmic radiation

has a much smaller contribution (7). Exposure from health care accounts for roughly fifty percent of the overall radiation exposure in first world medical sectors and is considerably the biggest source of humanly produced radioactivity (8). Since X – ray discovery by W. Roentgen in the late 18th century, its role in medicine has grown so considerably that currently X-ray based diagnostic radiology is responsible for over forty percent of the average American's life time radiation exposure (7, 9).

Radiation causes harm to living tissue by altering the cellular structure and structural damage to the DNA. The extent of the insult is depended on the kind of radiation (and its associated energy level) as well as the amount that is absorbed by the tissue in question (10). The body frequently repairs the resultant damage of minor and even moderate radiation exposure effectively. The sensitivity to radiation differs among certain cell populations with certain cells being more sensitive than others. As exposure increases cellular turn over declines with resultant carcinogenic consequences (11).

The biological effects of radiation are categorised into deterministic and stochastic effects:

- Deterministic effects (tissue reactions) refer to tissue injuries caused by injuries to cell populations. These tissue responses are evident sooner or later after a specific threshold dose. Examples of these effects are skin death and cataracts (11, 12).
- Stochastic effects thought to be unicellular in origin, are mutations that cause cancer or hereditary effects. An effect's intensity and dosage have a considerably less significant relationship. (11, 12).

Cancer risk from every form of exposure to ionising radiation is collective (13) and this risk keeps on growing decades after the original exposure (14).

1.2. Paediatric considerations in radiation risk

Children have a much larger risk of developing cancer in comparison with adults (15). Active tissues with a high mitotic rate are most susceptible to radiation damage and therefore infants and children have the highest associated risk. The risk follows general growth patterns which gradually approaches the same level as adults in their adolescent years (16, 17). In growing

order of sensitivity a child's most radiosensitive organ systems are the thyroid gland, breast tissue, hematopoietic tissues , central nervous system and the skin (18).

The bodily dimensions of a child and a grown-up are remarkably unalike. A small child's body is shorter and wider resulting in a larger area being exposed to the radiation field during an X -ray procedure. This in turn causes scattered radiation to have a more pronounced effect. Because children's tissues have a larger water content, a greater amount of photon energy is taken up and disseminated. More aggressive levels of radio- activity is thus required to break through a slab of body with the same depth (19). Certain tissues which have a particularly high risk, such as bone marrow, have a different distribution in younger children. Infants have larger amounts of red marrow throughout their entire body, including the extremities (19, 20).

Radiation-induced malignancies have a long latency. Acute myeloid leukaemia (AML) and chronic myeloid leukaemia (CML) have a latent period of between 2 and 25 years, breast carcinoma 15 to 40 years and thyroid cancer 10 to 40 years. Children and adolescents are inclined to be inflicted by these cancers (21, 22).

There are numerous studies that make an effort to verify health outcomes of exposure to low levels of ionising radiation. The United States National Academy of Sciences has assigned a series of reports to address this goal. The data for these studies are obtained from the atomic bomb survivors, people exposed to medical sources of radiation, radiation healthcare workers, employees in the nuclear industry and people exposed to environmental radio-activity. The above- mentioned studies are collectively mentioned as the Biological Effects of Ionising Radiation (BEIR) reports. The most up- to- date addition is the BEIR 7 report which inspects all the classes of data (23). Epidemiological articles of paediatric radiation regarding radio- therapy for the healing of neoplasms and diagnostic investigations have been considerably evaluated in the BEIR 7 report. The report established that at lower doses cancer risk progresses in a linear manner with no threshold value and the smallest dose can potentially raise the risk in patients (24).

The above mentioned linear no-threshold model is imperfect and has recently been challenged in the literature. Until improved models become available, it is still presently the superior model to address the concerns in practical radiation protection (25).

To predict the rate of cancer and mortality with accuracy is exceptionally in patients subjected to doses less than 100 mSV. It is virtually impossible to correctly predict cancer rate and death in a sub- set of patients exposed to doses smaller than 100 mSv. When operated appropriately, practically all imaging procedures fall shy of delivering the above-mentioned threshold of 100 mSv. It is thus essential to minimise radiation as much as possible, maintain safety and be beneficial to all patients (26) .

1.3. Quantities for radiological protection

The principal quantity used in the measurement of radiation dose is the absorbed dose which is the absorbed energy per unit mass. For the purpose of radiation protection, the dose is averaged over the tissue or organ irradiated. It is specified in gray (Gy), where 1 gray equals 1 Joule per kilogram (27). Absorbed dose on its own is not sufficient to quantify the biological damage by different kinds of radiation and the equivalent dose is used for this goal. Equivalent dose is calculated in the following manner: Absorbed dose times (x) the radiation weighting factor which is expressed in Sievert (Sv). X -rays used in fluoroscopy has a weighting factor of 1 (28) .

To approximate the harm from malignant transformation and hereditary effects, the effective dosage is utilised. This value is calculated by multiplying the average organ equivalent dose by the International Commission on Radiological Protection (ICRP) tissue weighting factor and adding the results over the entire body. This value mirrors the injury caused by the induction of stochastic effects, regardless of the dose distribution throughout the body (28).

It needs to be taken into consideration that the effective dose has considerable limitations in quantifying medical exposure. It is useful for the comparison of dosages from diverse radiological tests and the application of comparable machineries for the same medical procedure. It must not be applied in a retrospective manner to establish individual risk. This should rather be done by calculating the average doses to the tissues susceptible to radiation

collectively and thereafter combining it with the demographic- and organ specific risk coefficients of the individual (28, 29).

1.4. Monitoring radiation dose in fluoroscopy

There are numerous methods in use to measure patient skin dose and can be categorised into direct and indirect methods. Direct methods measure the skin dose by implementing tiny dosimeters fixed to the subject's surface. Non- direct systems calculate the skin dose from magnitudes within the ray, otherwise technical dynamics are employed. Dose-area product (DAP), or the more recent alternative name kerma- area product (KAP), is the most popular method for indirect monitoring. Deterministic effects cause necrosis to a specific area of tissue and accordingly most appropriately measured by the total dose to a region of tissue (skin). Stochastic effects transpire in a random fashion with even a solitary cell potentially at risk and therefore most appropriately measured by the dose area product (30).

The fluoroscopic unit does not measure the dose in tissue directly, but instead determines the kinetic energy a substance releases (specifically air), which is abbreviated as air kerma. A DAP meter utilises a compartment that releases gas - generated rays which is secured on the tube's collimator. This mechanism ensures that the imaging field is exposed totally unabridged. The measurement is expressed as either the dose-area product or the air-kerma-area product because the DAP measurement is a function of the magnitude of the X-ray field and exposure at the collimator (31). The DAP is measured in $Gy.cm^2$ and is calculated by multiplying the dose (in Gy) in the middle of a certain plane of the photon beam (the surface of the anatomy of interest) by the area of the photon beam field at that given plane (in cm^2) (32).

The DAP/ KAP value is constant at any distance because of the inverse square law: The dose decreases and the area of the field increases with the square of the distance. DAP represents the overall energy imparted to the patient. The effective dose is approximated by using the DAP value in conjunction with a coefficient that is subject to the segment of the body exposed to radiation and the technical factors of the X-ray beam. These coefficients stem from the Monte Carlo simulations that utilise human-based arithmetical models (33). Children's bodies are smaller than adults and their radiosensitive organs thus have a closer relation to the rest of the body. This causes the field of radiation to include more vulnerable organs. The

conversion coefficients applied to children are therefore higher than their adult counterparts (34).

1.5. Paediatric radiation protection

The indispensable role that medical imaging plays in health care has brought forward a striking rise in the use of radiological techniques. The National Council of Radiation Protection and Measurements (NCRP) states that percentage of man-made radiation has grown 38% over the past few decades. The majority of the sources are from CT and interventional fluoroscopy with radiography and diagnostic fluoroscopy contributing 10%. Even though the advent of modern procedures and cross-sectional imaging reduced the utilisation of fluoroscopy, it splays a significant and relevant role in current paediatric care and efforts should be made to appropriately reduce radiation dose (35).

There are numerous international organisations and administrations that promote paediatric radiation protection. Perhaps the most popular and influential are the Society for Paediatric Radiology's ALARA initiative and the Image Gently campaign underwritten by the Alliance for Radiation Safety in Paediatric Imaging (35).

The ALARA principle, which stands for "as low as reasonably achievable", is concerned with keeping radiation to children as low as practically possible. Paediatric fluoroscopic procedures are complex and dependant on the expertise of the operator which includes not only general and paediatric radiologists, but also gastroenterologists, urologists and paediatric cardiologists. To achieve ALARA sufficiently independent, but interconnected methods must be adhered to (36):

1) The machine design must be tailored to maximally reduce dose during image acquisitioning.
2) Adequately trained staff to minimise the screening time and operator experience to keep the quantity of acquired images to a minimum.

The clinical staff, medical physicist and the supplier need to co-operate to tailor the fluoroscopic unit to the specific anatomical considerations of children. The most important

consideration in ALARA however is if the need for radiation to answer a clinical question is truly indicated (36).

The latest contribution from the Image Gently campaign is the pause and pulse programme aimed to promote awareness for the need to minimise radiation exposure. The following techniques are recommended to facilitate paediatric radiation protection and can be accessed on the image gently alliance website (37):

1) Minimal radiation to produce a diagnostic image and proper patient positioning.
2) Use pulsed fluoroscopic exposure (usually 5 - 10 milli-seconds), increase filtration with aluminium and copper and eliminate anti-scatter grids.
3) Steer clear from magnification and collimate to the anatomy in question.
4) Use the image grab function when an image needs to be stored.
5) Perform fluoroscopy only with strict clinical indication and opt for non- ionising radiation alternatives such as ultrasound and MRI whenever feasible.

On the national level, the RSSA and SASPI recognise that radiologists, as well as, technologists mainly work in facilities dominated by an adult population. The organisation has developed a set of imaging protocols to help health care provides optimise radiation protection for the paediatric patients in both government and private health care facilities. The protocols strive to follow the previously discussed ALARA and Image Gently principles and include radiography, fluoroscopy, CT, MRI and sedation guidelines (38).

SASPI is an organisation within the RSSA comprising of paediatric radiologists, paediatric radiology fellows, general radiologists and registrars (residents). The organisation strives to be at the best of their game in South African paediatric radiology. SASPI's goals are to enhance paediatric imaging protocols, the reduction in radiation exposure and the promotion of education, research and outreach projects. The RSSA/SASPI paediatric imaging guidelines were assembled in 2012 and the final draft was published in January 2013. This document is available on the RSSA's website. The guidelines are founded on the Red Cross Children's Hospital's guidelines in the Western Cape (39).

The purpose of these imaging protocols is to assist radiation health care workers to apply ALARA principles effectively when performing imaging procedures on children. The RSSA/SASPI protocol for diagnostic fluoroscopic procedures is (38):

1. Image only when there is an appropriate clinical indication.
2. Pulsed fluoroscopy: Shortest possible pulse width (generally 7.5 msec).
3. Anatomical views limited to answering the clinical question.
4. Collimate to exclude irrelevant portions of the body.
5. Proper positioning: Maximise X- ray tube to child distance and diminish image intensifier to child distance.
6. Instead of exposing when an image needs to be stored, the image grab function is used.
7. Proper fitting lead shielding to child, caregiver and staff.

1.6. Dosage reference levels

To supplement the effort of radiation protection the development and application of dosage reference levels (DRLs) have been propositioned. The notion of DRLs was initially put forward by the International Commission on Radiological Protection (ICRP) in their 1991 report (40) and subsequently expanded on in follow up recommendations. The latest ICRP report discussing DRLs was published in 2007 (41). A DRL is a type of investigational level that uses a simple measure where it serves as an easy test to recognise scenarios where radiation dosage to patients fall on either side of the extreme. DRLs are useful in aiding the circumvention of radiation dosage that does not provide any more benefit in the clinical application of medical imaging. DRLs need to be directed at obtaining the minimal imaging quality to have diagnostic relevance in clinical imaging and in so doing minimising radiation dosage (42).

DRLs assist in achieving the ALARA principle in radiology practice. When DRLs are applied to specific imaging techniques they promote the monitoring of radiation dosage and enhance radiation protection. All examinations that produce a high collective dose require DRLs and includes the most common low dose tests and the less common high dose tests. The more commonly performed X-ray examinations that should have DRLs include plain radiography, diagnostic and interventional fluoroscopy and CT. The specific paediatric fluoroscopic procedures that should have DRLs are VCUs, Upper GIT studies and contrasted enemas (43).

Even though there are strong recommendations for the application of DRLs and ample evidence supporting the need for DRLs, there are few data available on paediatric DRLs. There are two important reasons why the data on paediatric DRLs are so sparse: The frequency of paediatric exams is less than in adults, dosages fluctuate remarkably between different age-, size- and weight ranges. The grouping of paediatric examinations into categories of weight, age and size is very poorly standardised. This, together with the little amount of available data make the formation and comparison of DRLs complicated and very challenging (43).

1.7. Study objectives

The aim of the study was to determine the dosage reference levels for the more commonly performed fluoroscopic procedures in our paediatric diagnostic radiology department and to compare our values to published international standards.

2. Materials and Methods

2.1. Study design

This was a comparative retrospective single-centre study of patients' records, which were collected from fluoroscopic examinations performed in the department of diagnostic paediatric radiology in the Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) in Johannesburg, South Africa. Ethics approval for this study was obtained on 14/10/2015, the clearance certificate M150914 is attached as Appendix A.

2.2. Components of the database used in the study

The database consisted of children of the ages 15 years and younger who had undergone diagnostic fluoroscopic examinations between 01 May 2013 and 31 May 2015. The examinations included routine and urgent studies performed over the specified time period. The data were retrieved from the digital archive on the paediatric fluoroscopic unit.

All examinations were performed using the single fluoroscopy unit in our dedicated paediatric fluoroscopy suite. The unit used by our department is the Philips MD Eleva (serial number: 122037). To ensure accurate dosage readings the Philip's technical team performs quality control assessments annually. A Kerma X Plus 120 – 131 P calibration chamber is used to determine DAP test readings independent from the machine's built in DAP reader. A deviation of up to 20% between the two readings are considered accurate and accepted by the SANAS Accreditation Standards. The DAP readings and associated deviation are logged in the unit's case report file. The case report file confirms that the DAP readings, during the period in which the study was conducted (between 01 May 2013 and 31 May 2015), were logged annually and the values comply with the SANAS Accreditation Standards.

In our institution, we aim to follow the RSSA / South African Paediatric Imaging's guidelines. Technique is tailored to a specific patient profile and clinical question to obtain optimal medical imaging quality while minimising radiation exposure. This includes restricted anatomical views, collimation and "image grab". The DAP values were collected for each patient in every study performed.

The patients were categorised into four age groups (0-1, 2-5, 6-10 and 11- 15 years) and stratified by our three most commonly performed fluoroscopic examinations. The data was then compared to the data published in the UK's HPA Centre of Radiation, Chemical and Environmental Hazards HPA-CRCE-034 2012 report (44).

The UK's HPA Centre of Radiation, Chemical and Environmental Hazards HPA-CRCE-034 2012 report was chosen as the international standard for comparison. This report does not only serve as the United Kingdom's national radiation dose reference, but also acts as a direct source for many European DRLs. Where European countries have their own established national DRLs, the report is used as a reference tool for comparison (43, 44).

In the HPA report the patients' weight and/or sizes were available in the data sets and the doses were adjusted by standard anthropomorphic phantoms to the nearest standard size (0, 1, 5, 10 or 15 years). These adjustments were grounded on the association between the width of the anatomy included in the X-ray beam and the equivalent thickness in the closest size for a standard child. It can be obtained from direct measurement or calculated from the patient's weight and height (44).CMJAH's fluoroscopic unit does not record child size or weight, but has pre-programmed mAs and kVP settings that roughly adjusts dosages to impart minimised radiation to certain approximated age groups. Since this was a retrospective study children's weight could not be used. Instead the machine's age group references served as a guide for the age groups we assigned the children to in our study: 0-1, 2-5, 6-10 and 11-15 years. Our age groupings are not a perfect match to the standard age groupings of the HPA report, but serve as a reasonable comparison in the absence of anthropomorphic phantoms, weight and sizes available to us in our data set.

2.3. Inclusion and exclusion criteria

2.3.1. Inclusion criteria

- Children 15 years and younger.
- Children that had undergone diagnostic fluoroscopic procedures.
- Only the three major examinations will be included.

2.3.2. Exclusion criteria

- Patients without logged DAP values.

- Patient records that did not include age.
- Interventional procedures such as pneumatic intussusception reduction.
- Incomplete studies. Studies that were started and unintentionally interrupted, or studies that did not yield diagnostic information.

2.4. Statistical analysis

For each age group (within each procedure), the following analyses were done:

- Descriptive statistics (mean, standard deviation, median, interquartile range) was represented as frequencies and percentages.
- The sample median was compared to the HPA median using the Wilcoxon signed-rank test.
- The percentage of cases falling below the HPA median and upper third quartile was determined, and tested for significant difference from 50% and 75%, respectively (binomial test). The reason for this is that the UK's HPA Centre of Radiation, Chemical and Environmental Hazards report (44) uses dosage reference levels of the upper third quartiles.
- The 5 % confidence interval was used throughout, therefore p-values smaller than 0.05 show substantial results.

3. Results

3.1. Demographics

The study included 353 children that had undergone diagnostic fluoroscopic examinations. The age range was 0 to 15 years. The mean was 3.79 years and the median 2 years. The gender was not considered as it had no relevance in the study. There was an inverse ratio between the group age and the group size, with the youngest group being the largest and the oldest group being the smallest. The number of children in each procedure for each examination is summarised in Table 3.1.

Table 3.1 The number of children for each procedure according to the age group

Procedure	Age Group				
	0-1	**2-5**	**6-10**	**11-15**	**Total**
Upper GIT	71	77	35	5	188
Enema	53	27	11	17	108
VCU	16	9	13	19	57
Total	140	113	59	41	353

The number of cases within procedure -age group combinations varies substantially (range 5-77). Inference about the smaller groups will thus be limited.

3.2. Fluoroscopic examinations

Our institution's most frequent examinations were: Upper GIT studies, contrasted enemas and vesico-urethrograms (VCU). The most common performed test was the Upper GIT, comprising a total of 200 cases, followed by the contrasted enemas, with a total of 96 cases. The least performed test was thus the vesico-urethrogram, with a total of 54 cases. The relative percentages of cases for each examination are summarised in Figure 3.1.

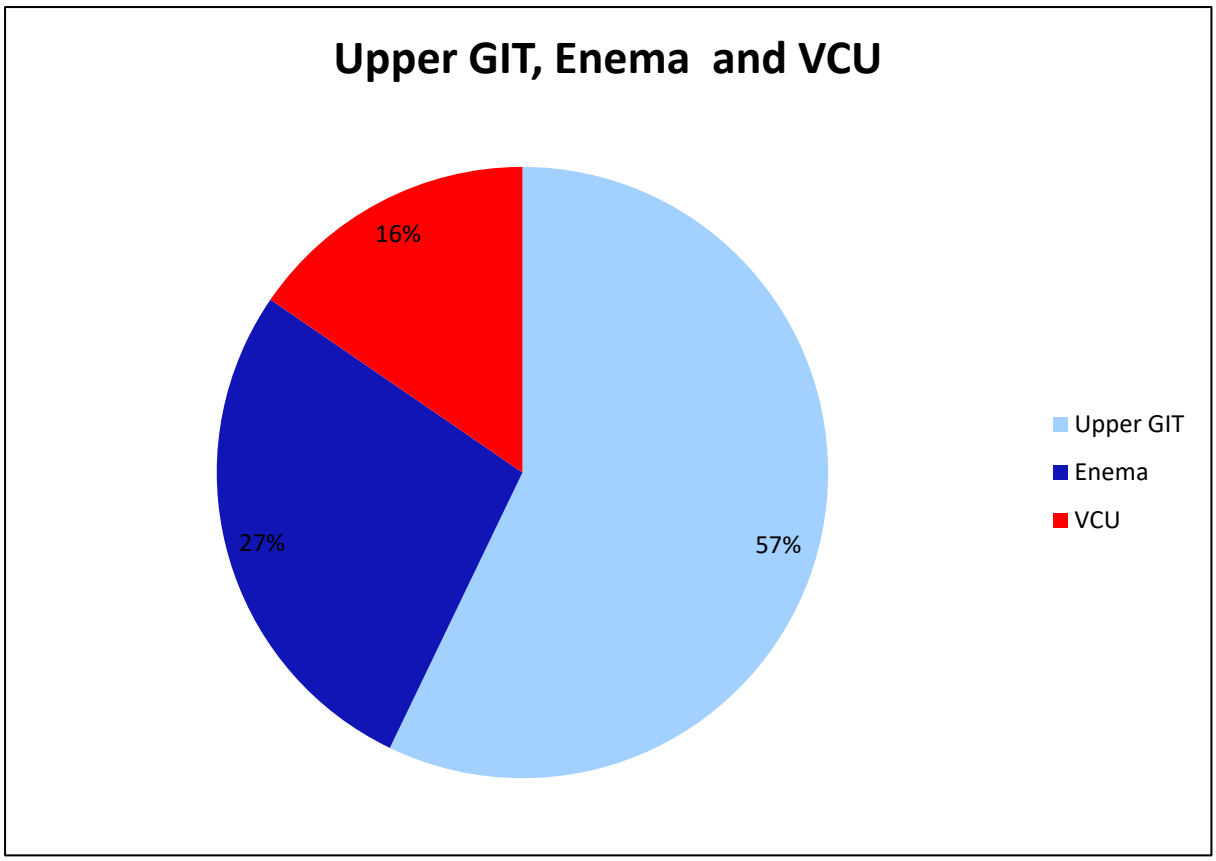


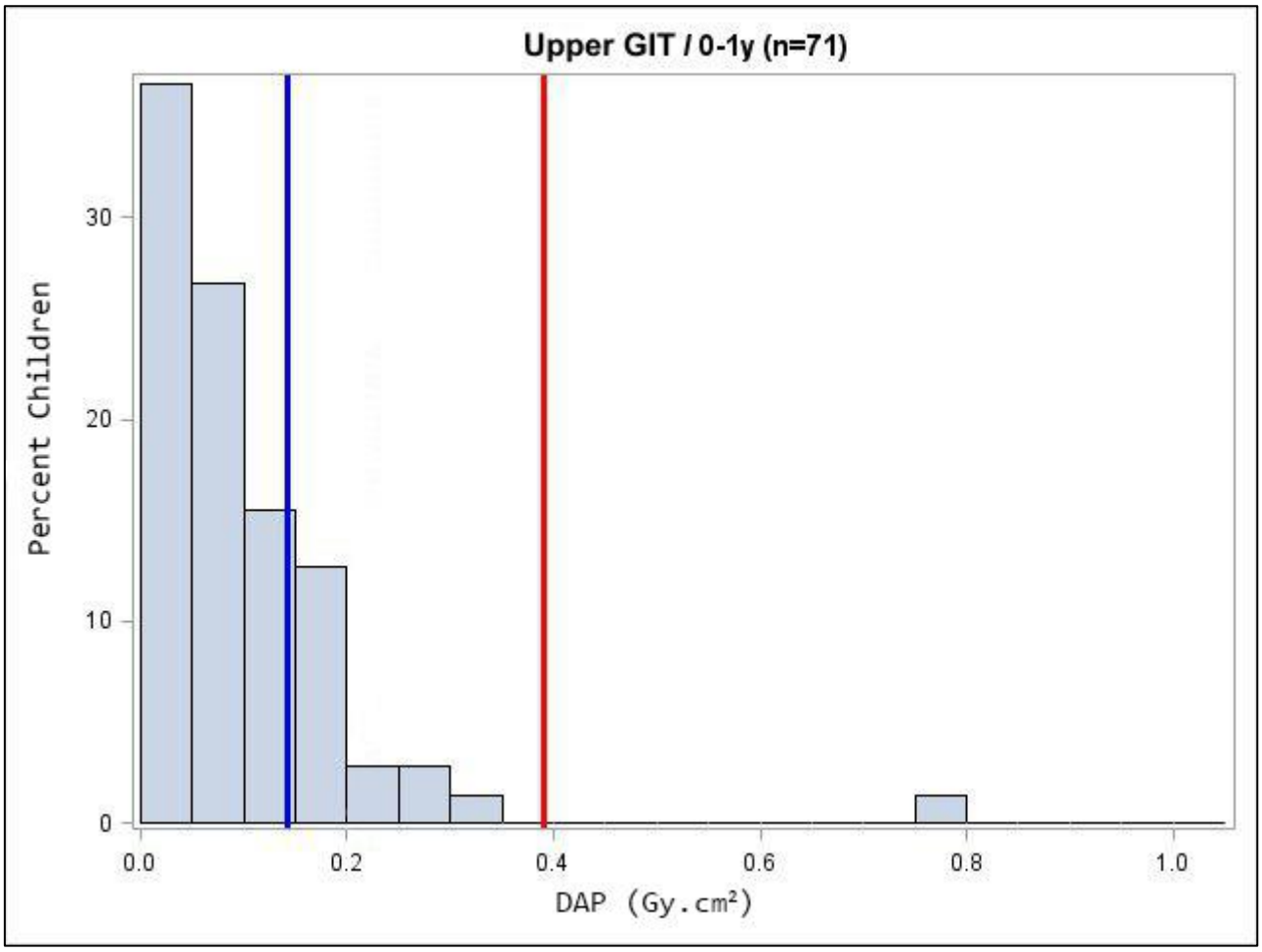
Figure 3.1 Percentages of individual examinations done during the study period

3.3. DAP comparison

The following comparisons were made:

- Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) Upper GIT with UK's Health Protection Agency (HPA) VCU data.
- Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) VCU with UK's Health Protection Agency (HPA) Upper GIT data.

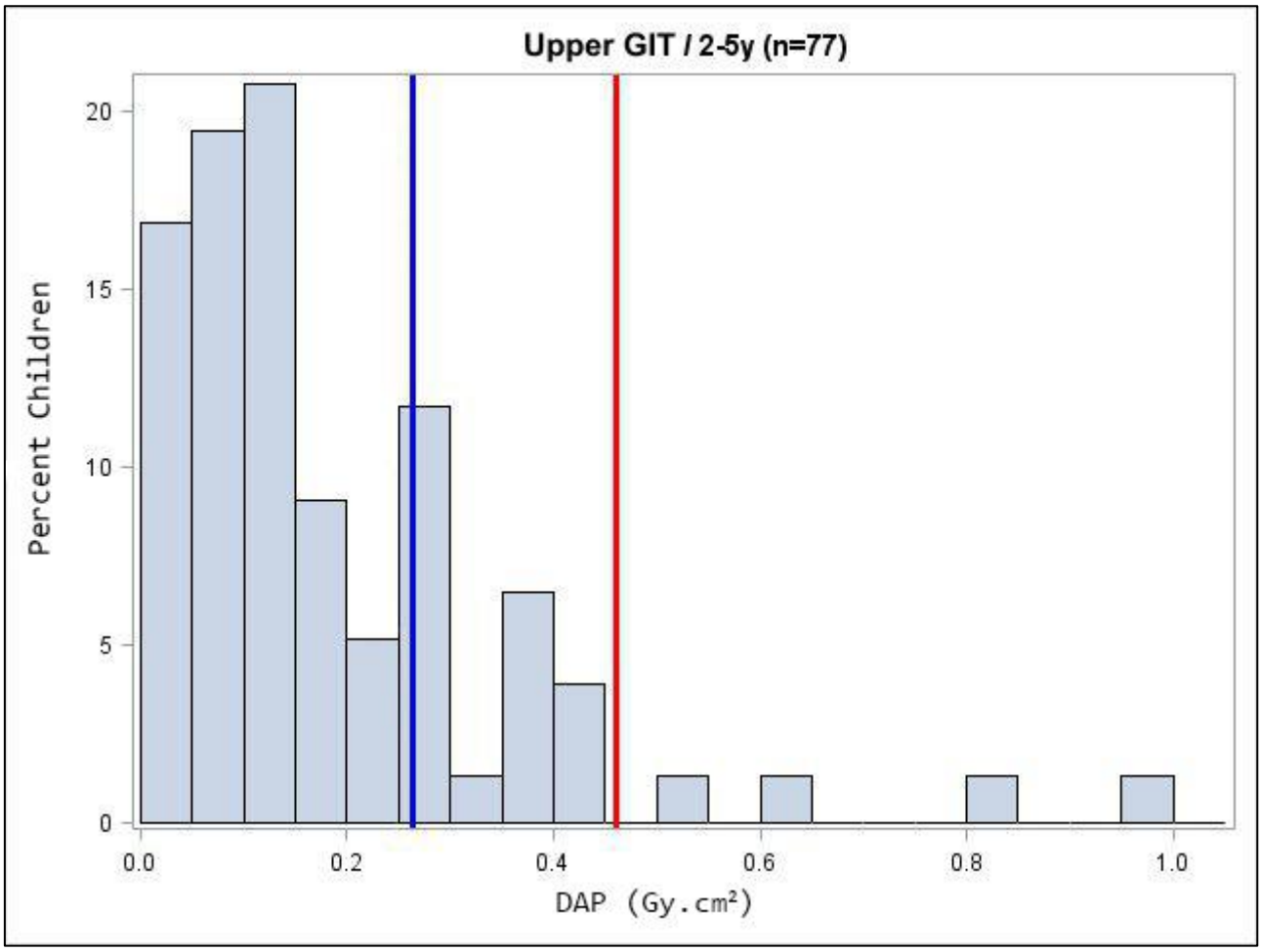
The histograms show the upper quartile of the study data (blue) and the upper quartile from the HPA report (red).



Note: Blue line represents this study, red line represents the international standard value

Figure 3.2 Comparing the upper third quartiles for the upper GIT studies in the 0- 1 years age group

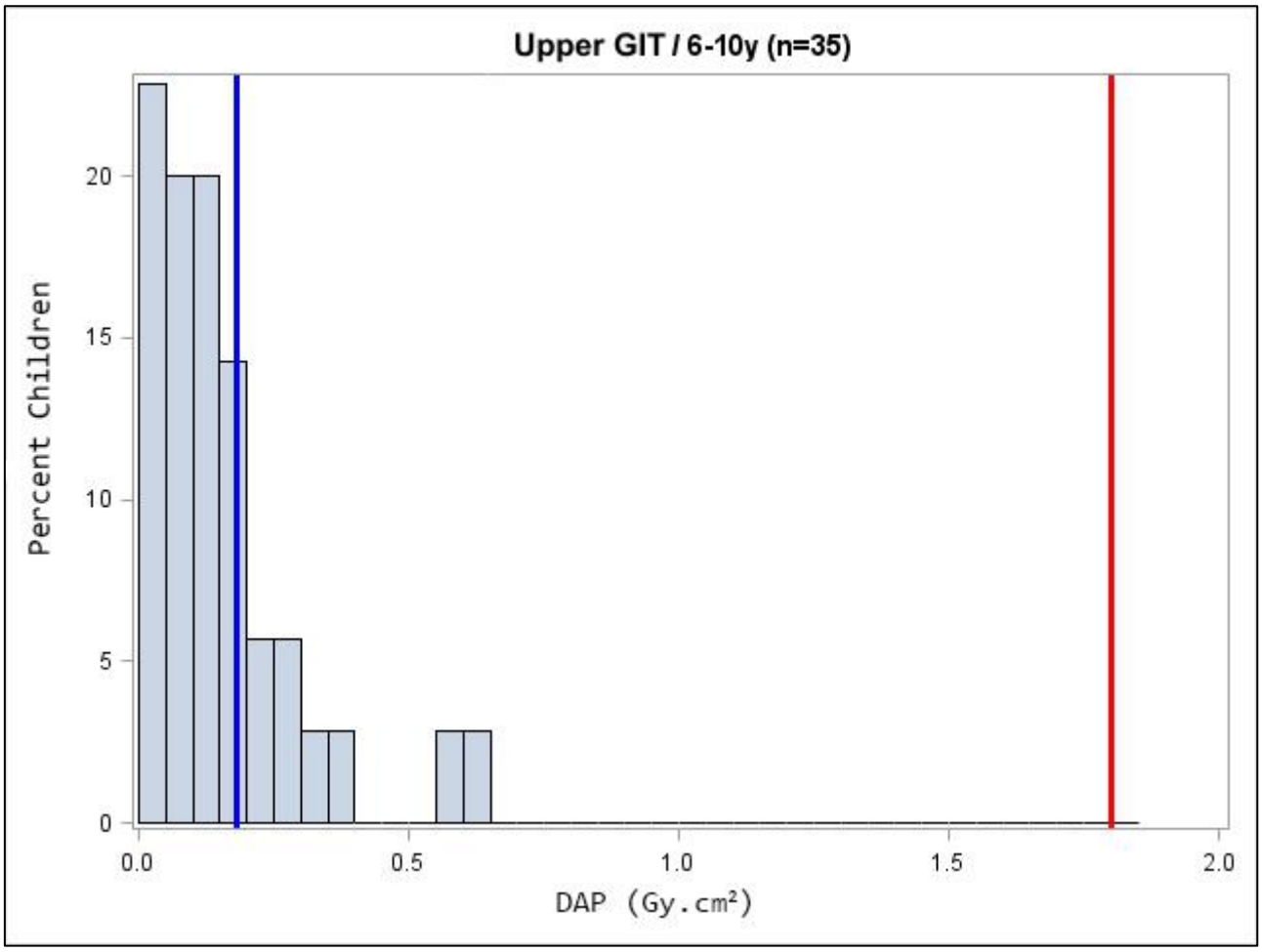
Figure 3.2 demonstrates the comparison of the upper third quartile of this study to the international standard of upper GIT studies in the 0 – 1 year age group. Our values are 0.142 $Gy.cm^2$ in comparison to 0.39 $Gy.cm^2$.



Note: Blue line represents this study, red line represents the international standard value

Figure 3.3 Comparing the upper third quartiles for the upper GIT studies in the 2-5 years age group

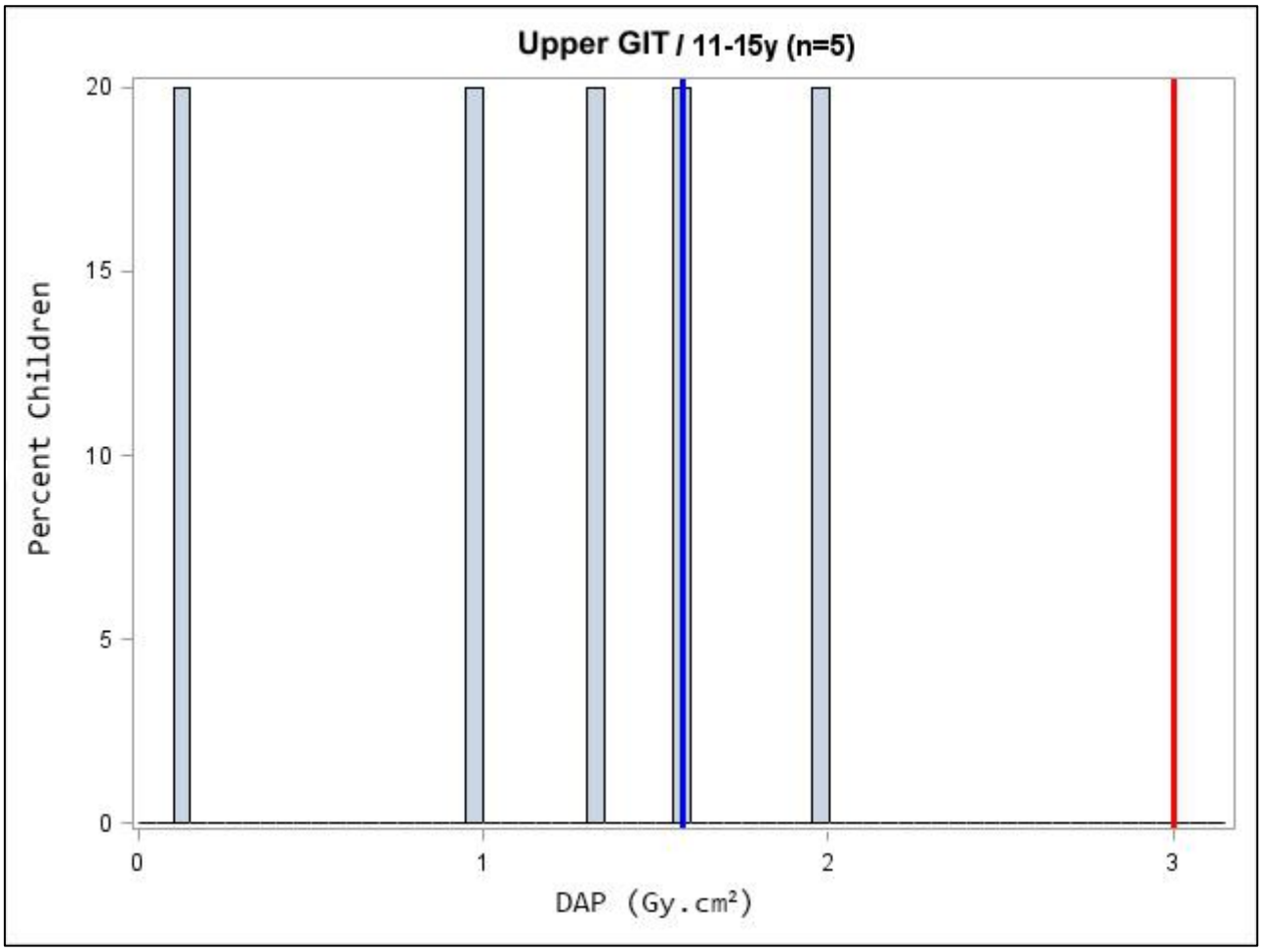
Figure 3.3 demonstrates the comparison of the upper third quartile of this study to the international standard of upper GIT studies in the 2 – 5 year age group. Our values are 0.264 $Gy.cm^2$ in comparison to 0.46 $Gy.cm^2$.



Note: Blue line represents this study, red line represents the international standard value

Figure 3.4 Comparing the upper third quartiles for the upper GIT studies in the 6 -10 years age group

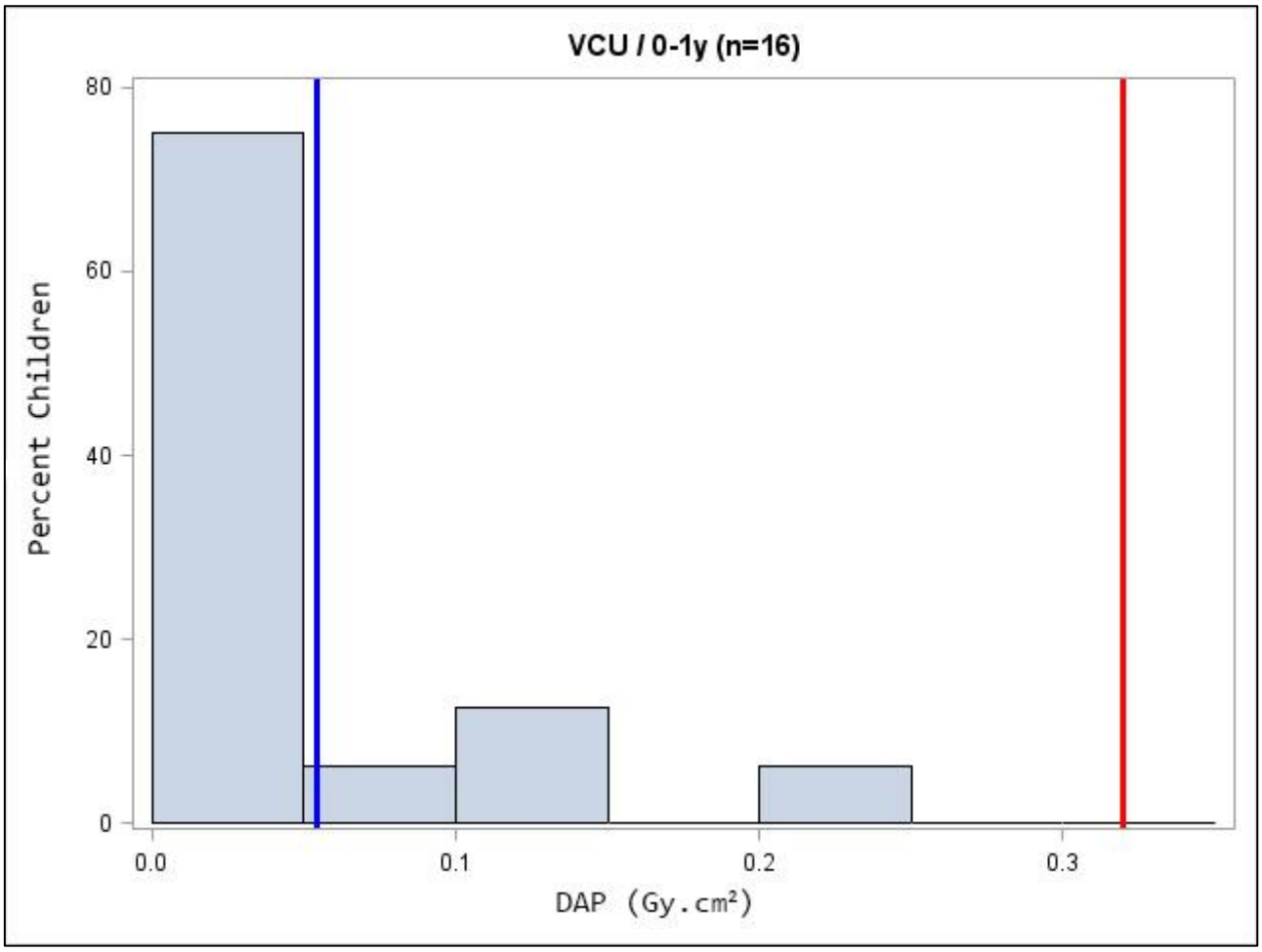
Figure 3.4 demonstrates the comparison of the upper third quartile of this study to the international standard of upper GIT studies in the 6 – 10 year age group. Our values are 0.183 $Gy.cm^2$ in comparison to 1.8 $Gy.cm^2$.



Note: Blue line represents this study, red line represents the international standard value

Figure 3.5 Comparing the upper third quartiles for the upper GIT studies in the 11 -15 years age group

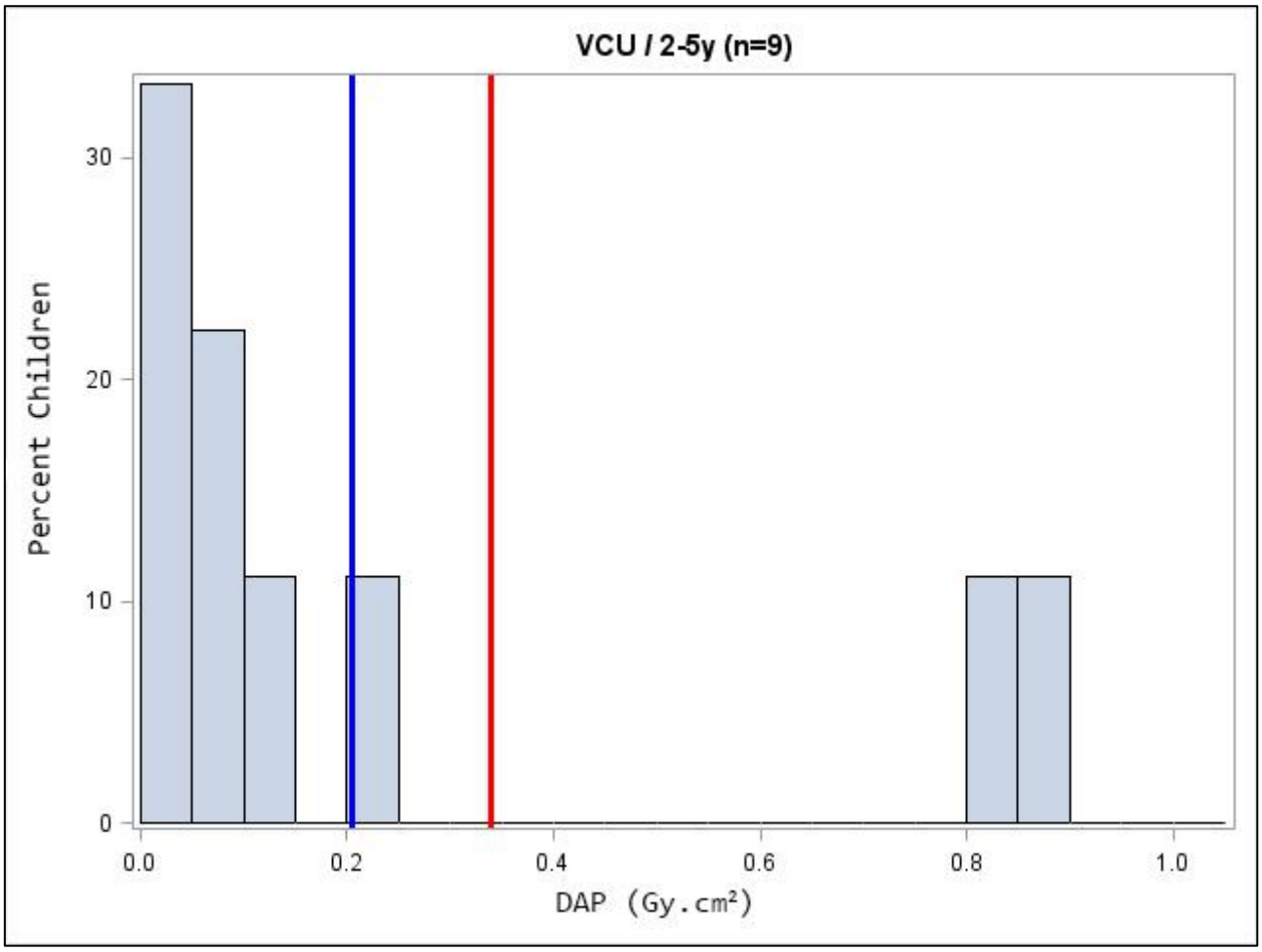
Figure 3.5 demonstrates the comparison of the upper third quartile of this study to the international standard of upper GIT studies in the 11 – 15 year age group. Our values are 1.580 $Gy.cm^2$ in comparison to 3.0 $Gy.cm^2$.



Note: Blue line represents this study, red line represents the international standard value

Figure 3.6 Comparing the upper third quartiles for the VCU studies in the 0 -1 years age group

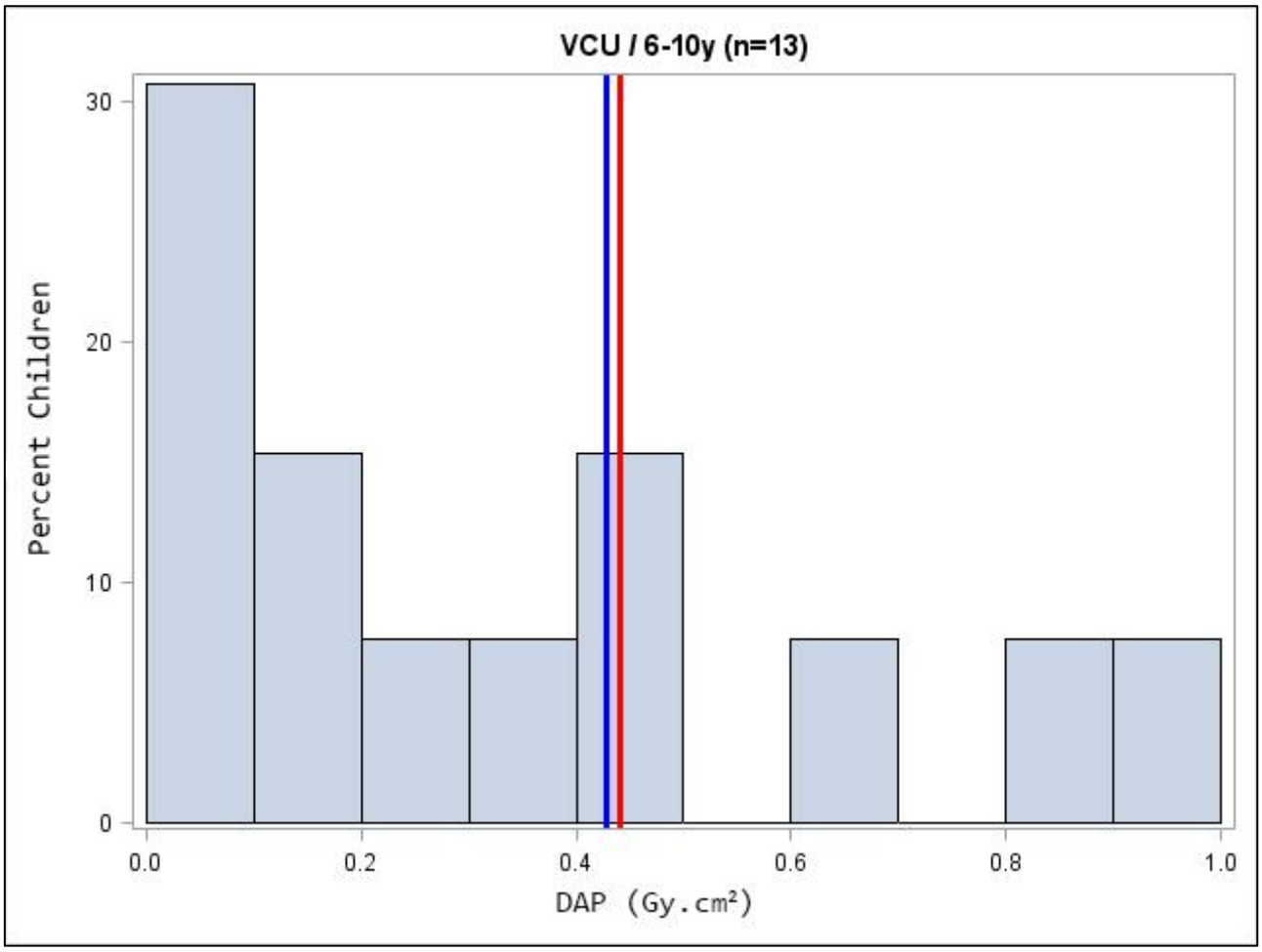
Figure 3.6 demonstrates the comparison of the upper third quartile of this study to the international standard of upper GIT studies in the 0 – 1 year age group. Our values are 0.054 $Gy.cm^2$ in comparison to 0.32 $Gy.cm^2$.



Note: Blue line represents this study, red line represents the international standard value

Figure 3.7 Comparing the upper third quartiles for the VCU studies in the 2-5 years age group

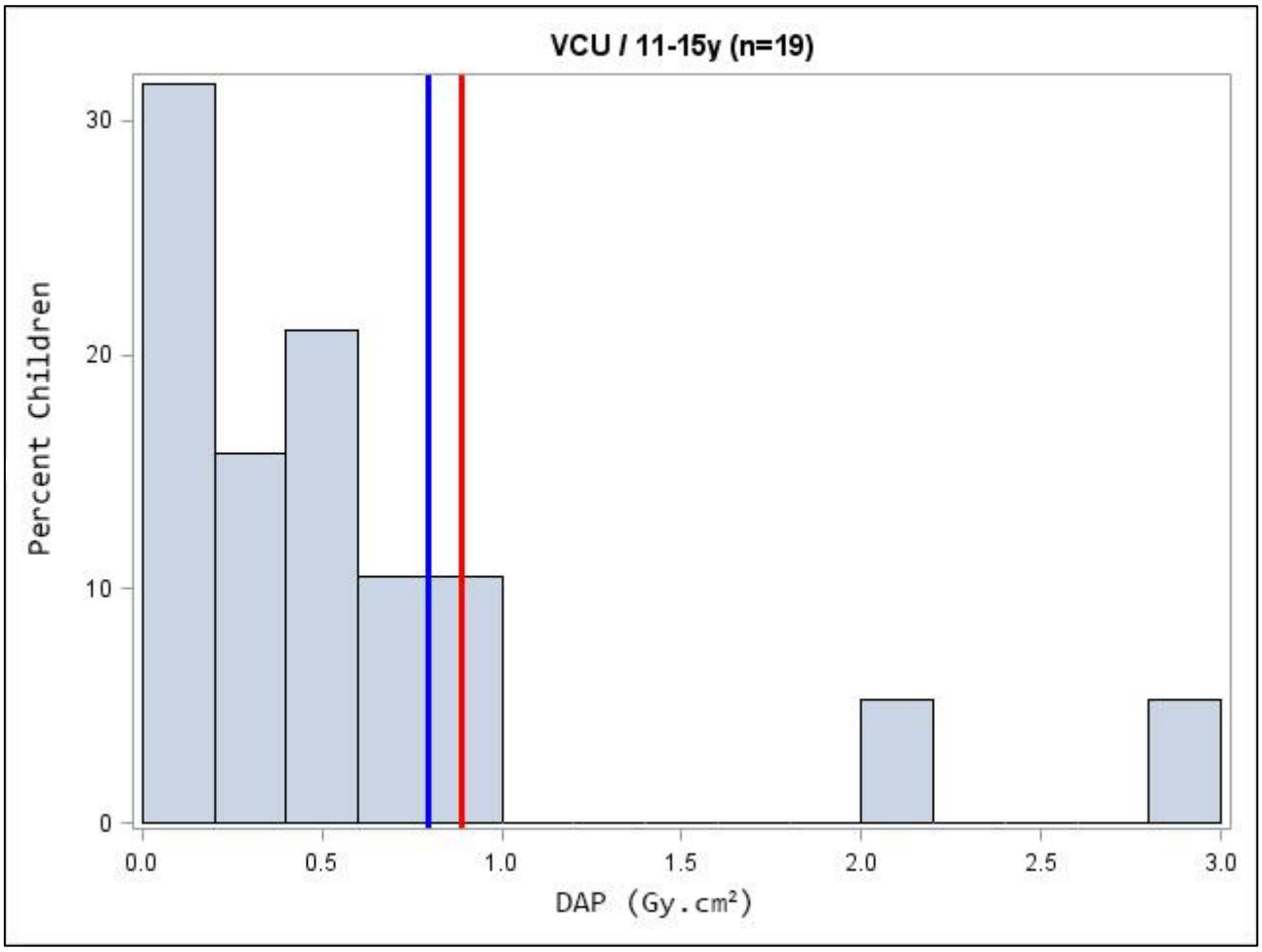
Figure 3.7 demonstrates the comparison of the upper third quartile of this study to the international standard of upper GIT studies in the 2 – 5 year age group. Our values are 0.205 $Gy.cm^2$ in comparison to 0.34 $Gy.cm^2$.



Note: Blue line represents this study, red line represents the international standard value

Figure 3.8 Comparing the upper third quartiles for the VCU studies in the 6 -10 years age group

Figure 3.8 demonstrates the comparison of the upper third quartile of this study to the international standard of upper GIT studies in the 6 – 10 year age group. Our values are 0.429 $Gy.cm^2$ in comparison to 0.44 $Gy.cm^2$.



Note: Blue line represents this study, red line represents the international standard value

Figure 3.9 Comparing the upper third quartiles for the VCU studies in the 11 -15 years age group

Figure 3.9 demonstrates the comparison of the upper third quartile of this study to the international standard of upper GIT studies in the 11 – 15 year age group. Our values are 0.797 Gy.cm^2 in comparison to 0.89 Gy.cm^2.

The histograms clearly show that the data are positively skewed, thus interpretation in terms of median and quartiles (rather than means and standard deviations), as done in the HPA report, is justified.

In our study the upper third quartile values were below the values of the UK's HPA report in both the upper GIT studies and the VCUs in all four age groups. This is demonstrated in Table 3.2.

Table 3.2 Comparison of CMJAH median and upper third quartile data with those of HPA report

Age group (in years)	Median DAP (in Gy.cm^2)		Upper third quartile DAP (in Gy.cm^2)	
	CMJAH	HPA	CMJAH	HPA
Upper GIT				
0 – 1	0.073	0.22	0.142	0.39
2 – 5	0.137	0.26	0.264	0.46
6 – 10	0.111	0.84	0.183	1.8
11 – 15	1.317	1.7	1.580	3.0
VCU				
0 – 1	0.021	0.17	0.054	0.32
2 – 5	0.086	0.18	0.205	0.34
6 – 10	0.263	0.32	0.429	0.44
11 – 15	0.408	0.36	0.797	0.89

3.4. Inferential analysis

The sample median was compared to the HPA median using the Wilcoxon signed-rank test.

- For our Upper GIT vs. HPA Upper GIT, the study medians were significantly lower than the HPA medians for the 3 youngest age groups ($p<0.0001$). The study demonstrated no substantial difference in the medians for the oldest age groups, but note the small sample size (n=5).
- For our VCU vs. HPA VCU, the study median was significantly lower than the HPA median for the youngest age group ($p<0.0001$). The study demonstrated no substantial difference in the medians for the older 3 age groups, but note the small sample sizes (n=9-19).

The percentage of cases falling below the HPA median and 3rd quartile was determined, and tested for significant difference from 50% and 75%, respectively (binomial test).

- For our Upper GIT vs. HPA Upper GIT, the proportion of study cases above the HPA median and HPA upper third quartile were significantly lower than 50% and 25% (respectively) for the 3 youngest age categories. The study demonstrated no substantial differences for the oldest age group, but note the small sample size (n=5).

- For our VCU vs. HPA VCU, the proportion of study cases above the HPA median and HPA upper third quartile were significantly lower than 50% and 25% (respectively) for the youngest age group. The study demonstrated no substantial differences for the older 3 age groups.

Regarding the contrasted enemas, there are no suitable data for comparison, however the values are presented in Table 3.3

Table 3.3 CMJAH median and upper third quartile contrasted enema data

Age group	Median DAP	Third quartile DAP
0-1	0.028	0.142
2-5	0.137	0.264
6-10	0.111	0.183
11-15	1.317	1.580

4. Discussion

4.1. Results in context

The paediatric population is growing, bringing with it a steady rise in the utilisation of medical imaging. Children are more susceptible to the harmful effects of radiation and special care should be taken to protect them from medical radiation exposure. DRLs are valuable tools in supporting the practice of radiation protection. International DRLs on paediatric upper GIT, enemas and VCU's are very limited and completely lacking in South Africa.

By analysing the data, a clear referral trend emerges: The great majority of our request are for the younger age groups for both the Upper GIT and VCU studies: The conditions requiring fluoroscopic diagnosis or work-up generally occur in the younger children: midgut malrotation, oesophageal atresia with or without trachea-oesophageal fistula, gastro - oesophageal reflux, posterior urethral valves, vesico -ureteric reflux and work up for recurrent bladder infections (1-4). As our institution is an academic tertiary referral hospital, it is completely expected that very young complicated paediatric cases are referred by the various paediatric sub- specialities for imaging work-up. Our study's age distribution that is skewed to the younger age ranges are thus in keeping with our local referring trends.

Our most frequently performed examination is the Upper GIT study comprising 57% of total cases, followed by the contrasted enema (27%) and our least frequently performed test is the VCU (16%). Figures on the distributions on paediatric fluoroscopic procedures in the international literature is extremely scarce. In Eurosafe Imaging's report on European Guidelines on DRLs for Paediatric Imaging a questionnaire was sent out to 33 centres to gather information on distribution of paediatric imaging. From the replies of 18 centres the relative distribution of the more common imaging techniques was compiled (43). Table 3.4 below compares the distribution of our fluoroscopy to the European survey:

Table 3.4 Comparison of the distribution of paediatric fluoroscopic procedures of the current study to a European survey

Procedure	**CMJAH (%)**	**European survey** (43) **(%)**
Upper GIT	57	32
Contrasted enema	27	5
VCU	16	34

The table shows that the VCU is the most commonly performed fluoroscopic study in Europe in contrast to our scenario where it is the least commonly performed procedure. Furthermore, upper GIT studies are performed significantly more in our centre than in Europe and we also do considerably more contrasted enemas. The reasons for these discrepancies are unknown.

The histograms showed that the data are positively skewed. Apart from using this knowledge to compare study medians and upper third quartile ranges, we also showed that there is a direct relationship between the age (and thus the weight) of a child and the dose a child receives. This is reassuring as one would want smaller children to receive relative smaller doses of radiation (45).

The European Guidelines on DRLs for Paediatric Imaging report mentions published literature on paediatric fluoroscopic DRLs in Europe:

- A study by Hiorns et al 2006 published DRLs for a tertiary hospital in UK. The fluoroscopic studies include Upper GIT, contrasted enemas and VCUs (less commonly performed fluoroscopy studies are also documented). Although the population size is documented, the difference in age groupings is too substantial to make a relevant comparison (45).
- A second study by Smans et al in 2008 published DRLs for various local institutions in France. The fluoroscopic studies are Upper GIT, contrasted enemas and VCUs. Although the DAP values may be of use to establish DRLs, the authors do not show the statistical strength of their data and their patient groupings differ substantially from our age groupings therefore excluding a relevant comparison of the data (46).

- A third study mentioned by the European Guidelines on DRLs for Paediatric Imaging to have published DRLs is by Yakoumakis et al in 2014. This study however is concerned with calculating effective doses from paediatric Upper GIT studies in Greece's Aghia Sofia Paediatric Hospital, thus precluding their DAP values for a relevant comparison (47).

The European Guidelines on DRLs for Paediatric Imaging report furthermore mentions two international studies outside of Europe on paediatric fluoroscopic DRLs. Both studies are Canadian: Lee et al 2009 (48) that looks at radiation doses in VCU studies and Emigh et al 2013 (49) that looks at radiation doses in Upper GIT studies. Both these studies are concerned with calculating effective doses making them unsuitable for comparison to our DAP values. A third international study to publish DRLs is a from a tertiary teaching hospital in Australia: Bibbo et al 2016 (50). Their study provides DRLs for upper GIT studies, contrasted enemas and VCUs, however due to their different age groupings, their data is unsuitable for a comparison to ours.

This large variety in approaches is reflected in the literature. There is an obvious absence in the consistency of patient grouping with regards to age, weight or other methods. This makes the comparison of DRLs very difficult and even inaccurate. To overcome this limitation, clear guidelines on patient categorisation need to be put forward and adhered to when establishing DRLs (43).

Although there are numerous published data on South African paediatric fluoroscopic DRLs, all of these pertain specifically to paediatric cardiology. The latest is a study by Netshivhera and Conradie in the Journal of Medical Physics, published in 2016 (51). However, there are currently no published DRLs for South African paediatric fluoroscopic upper GIT, enemas and VCU's.

4.2. Current applications

By following the RSSA/SASPI guidelines, which is outlined above in sub- section 1.5 of the introduction, our overall DAP values for the upper GIT studies and the VCU compared better than the UK's HPA-CRCE-034 2012 report values in the younger age groups and no worse in the older age groups.

In addition to strictly following the RSSA/SASPI imaging guidelines in our daily practice, there is a pervasive culture of radiation protection awareness in the department from the most senior paediatric consultant radiologist in charge down to the most junior technologist. The HPA report does not disclose the referral level of their hospitals, but they probably range from primary care to tertiary level. The staff would then consist of a mixture of general radiation health care workers among specialised paediatric radiation health care workers. Such health care institutions would be expected to have higher general paediatric radiation dosages then specialised paediatric facilities, since paediatric health care is not their primary focus.

It would thus be reasonable to attribute our lower local dosage reference levels to strict adherence to ALARA and Image Gently principles (as outlined in the introduction) by following the RSSA/SASPI guidelines in our routine daily practice. We cannot however dismiss the fact that we practice in a tertiary paediatric referral center which is likely an additional reason for our lower dosage reference levels than the HPA report. The study strongly supports the use of the RSSA/SASPI's guidelines to limit radiation exposure and we will thus continue applying these guidelines in our daily practice and maintain a positive culture of radiation protection awareness.

4.3. Limitations of the current study

Our sample size is limited: In the older age groups (11- 15 years' age group in the upper GIT studies, 2-5, 5-10 and 11- 15 years' age groups in the VCUs) the sample sizes were small, resulting in sub optimal statistical comparisons and no significant comparative differences.

There is a lack of international published data on DRLs for paediatric contrasted enemas which precludes an accurate comparison with our data. Furthermore, there are no published data on DRLs for paediatric contrasted enemas in Africa and South Africa.

4.4. Future applications

Since following the RSSA/SASPI guidelines resulted in the majority of our DRLs comparing better than the UK international standard, we will continue to implement these guidelines in our daily practice to keep radiation exposure to a minimum. The DRLs for upper GIT studies and VCU of this study should be implemented as standard for local practice. Even though the

DRLs for our contrasted enemas could not be compared to international data, these values should also be used as local standards, since there are no local standards available.

This study should be extended to the remainder of the paediatric health care facilities at Wits. The larger data pool will allow for a stronger statistical analysis and overcome this limitation in the current study.

Radiology practices both in private practice and in the public sector should be encouraged to adhere to the SASPI guidelines and create a culture of radiation protection awareness. Any health care worker (irrespective of whether the individual is a paediatric radiologist or general radiologist) who performs paediatric fluoroscopy should be familiar with ALARA and Image Gently principals to ensure adequate radiation protection to our children.

4.5. Areas of future research identified by the current study

This study has identified some promising potential future research projects. Paediatric radiology units in the other provinces should be approached to establish their own DRLs for upper GIT studies, contrasted enemas and VCUs. This will serve as reference for their DRL's and internal audit for radiation protection. Different provinces should then compare their DRLs to each other to identify outliers that may need to change radiation protection practices. With large enough data sets a national DRL can be established, serving as a national internal audit and comparison to international DRLs. An interesting aspect of this future application is to compare our DRLS with that of Cape Town's Red Cross War Memorial Children's Hospital, since the SASPI guidelines we apply to optimise radiation protection are based on their imaging protocols.

It should be mentioned that it is likely that future retrospective studies will also be hampered by inconsistent age groupings for DRLs, as seen in the literature and in the current study. The European Guidelines on DRLs for Paediatric Imaging report recommends that groupings should be done in standard weight groupings to ensure more accurate DRL comparisons (43). The most reliable method of ensuring data stratification in consistent weight groupings is to conduct prospective studies to ensure that children's weights are recorded. It is therefore recommended that instead of retrospective studies, prospective studies should be carried out to minimise limitations in data comparisons.

The majority of radiology practices mainly accommodate the adult population, both in private practice and government practice. Facilities fortunate enough to have specialised paediatric radiology staff fall in the vast minority (38). When the national DRL database include the majority of radiology units without a dedicated paediatric staff, a different picture may emerge when compared to international DRLs, to the HPA report for example. However, this would be a more accurate representation of national DRLs in South Africa.

5. Conclusion

Our paediatric population is growing, with it the utilisation and complexity of medical imaging. Children are a vulnerable sub-group of patients and are more susceptible to the hurtful sequalae of radio -activity. With the ever-growing radiation burden to children caused mainly by a steady increase in medical imaging, it is of the utmost important to protect children from radiation.

DRLs are valuable tools in optimising radiation protection. By comparing our DRLs to the HPA report we showed that by adhering to the ALARA based RSSA/SASPI guidelines, our dosage levels were lower in the majority of our exams (mainly in the younger age groups).

We should proceed to encourage other imaging centres in South Africa to apply the RSSA/SASPI guidelines and establish their own DRLs in order to promote radiation protection when performing paediatric fluoroscopic studies.

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Appendix A: Ethics Clearance Certificate

R14/49 Dr Mauritz Venter

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M150914

NAME: (Principal Investigator)	Dr Mauritz Venter
DEPARTMENT:	Radiology Charlortte Maxeke Johannesburg Academic Hospital
PROJECT TITLE:	A Review of Radiation Dose in Paediatric Fluoroscopy in a South African Academic Hospital
DATE CONSIDERED:	02/10/2015
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr Jaishree Naidoo

APPROVED BY: Professor P Cleaton-Jones, Chairperson, HREC (Medical)

DATE OF APPROVAL: 14/10/2015

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary in Room 10004, 10th floor, Senate House/2nd Floor, Phillip Tobias Building, Parktown, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report.**

Principal Investigator Signature Date 13/12/2016

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix B: Note on reference style

Please note that the referencing in this thesis is a modification of the Vancouver Referencing style, done according to the Faculty of Health Sciences Style Guide as set out by the Wits Health Sciences Library.

The information on this WHSL Vancouver Citation Style Guide for Theses, Dissertations and Research Reports is available from http://libguides.wits.ac.za/whsl-vancouver updated on 30 January 2017.