# Peer Reviewed Original Article

# DIAGNOSTIC REFERENCE LEVELS IN PAEDIATRIC FLUOROSCOPY: A SINGLE-CENTRE STUDY IN SOUTH AFRICA

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### Abstract

**Background.** Establishment of diagnostic reference levels (DRLs) in medical imaging is recommended as a tool for dose optimisation. Currently, there are no published South African DRLs in paediatric fluoroscopy. This study proposes local DRLs for selected paediatric fluoroscopy studies, which may contribute to the establishment of national DRLs.

**Objective.** To establish single-centre local DRLs for air-kerma area product (KAP), cumulative air kerma at a reference point (K<sub>a,r</sub>), and total fluoroscopy time in paediatric fluoroscopy.

**Method.** A retrospective analysis of archived data of fluoroscopy procedures was performed. The data were stratified into age and weight groups, and for each group and procedure, the mean, 25<sup>th</sup>, and 75<sup>th</sup> percentile values of KAP, K<sub>a,r</sub>, and FT was determined. In this study, the local DRL was defined at the 75<sup>th</sup> percentile value.

**Results.** The proposed local (DRLs) in terms of KAP, K<sub>a,r</sub> and FT are: 87 mGy.cm<sup>2</sup>, 0.43mGy, 2.5 min for barium enema; 44.4 mGy.cm<sup>2</sup>, 1.10 mGy, 3.5 min for barium swallow; 28.7 mGy.cm<sup>2</sup>, 1.32 mGy, 3.5 min for modified swallow; 35.5 mGy.cm<sup>2</sup>, 3.83 mGy, 2.6 min for barium meal; 73.8 mGy.cm<sup>2</sup>, 1.35 mGy, 8.6 min for enema: air reduction; 23.0 mGy.cm<sup>2</sup>, 0.63 mGy, 1.9 min for contrast via peg; 33.8 mGy.cm<sup>2</sup>, 0.38 mGy, 1.2 min for urodynamics; and 40.0 mGy.cm<sup>2</sup>, 1.00 mGy, 3.1 min for micturating cystourethrography.

**Conclusion.** The LDRLs in this study do not vary significantly from those found in cited references in the literature. However, there exists room for further optimisation.

**Contribution.** This study represents the first time that dose reference values for paediatric fluoroscopy have been published in South Africa.

Keywords. Fluoroscopy; DRL; ALARA/dose optimisation; radiation protection; radiation risks

**Lay Abstract.** A study was performed to establish local diagnostic levels in paediatric fluoroscopy at a specialist hospital.

#### **INTRODUCTION**

Fluoroscopy is a minimally invasive radiological imaging technique for visualising the internal anatomy and functions of the human body. Its first and most significant benefit is the ability to obtain real-time data with true temporal resolution.<sup>[1]</sup> Computed tomography (CT) scanners have optional facilities for fluoroscopy.<sup>[2]</sup> However, only dedicated conventional fluoroscopy systems currently permit patient repositioning in real time during an imaging examination; a facility that is known to assist in diagnosis. In addition, conventional fluoroscopy studies are more affordable owing to the lower capital and maintenance costs<sup>[3]</sup> hence are more accessible to patients in Low to Middle Income Countries (LMIC). Owing to the requirement for continuous screening and cine acquisition, fluoroscopic examinations may potentially expose a patient to high radiation doses; increasing the risk of inducing detrimental radiation effects. This risk is more exaggerated in children than adults,<sup>[4]</sup> therefore special attention must be given to paediatric medical examinations to minimise radiation exposure. In this regard, initiatives such as the Image Gently campaign<sup>[5]</sup> were conceived to raise awareness of the need to reduce radiation dose in paediatric imaging. Literature reports some success<sup>[6, 7]</sup> and also some controversy.<sup>[8]</sup>

What remains fundamental in radiation dose management is for paediatric fluoroscopy examinations to be justified and optimised. In service to dose optimisation, the establishment of diagnostic reference levels (DRLs), using appropriate dosimetric quantities, is recommended.<sup>[9]</sup> For fluoroscopic procedures, the kerma area product (KAP), cumulative reference air kerma as a reference point (K<sub>a,r</sub>), and total fluoroscopy time (FT) are the indices commonly used for this purpose. KAP is best suited for estimating the risk of long term stochastic effects in the exposed individual;<sup>[10]</sup> K<sub>a,r</sub> is directly proportional to entrance surface dose and therefore estimates the risk of skin injuries.<sup>[11]</sup> Technological advances such as pulsed fluoroscopic screening, variable copper filtration, and automatic dose rate control (ADRC) implemented in modern fluoroscopy imaging devices have rendered FT an unreliable dose index. However, it has been researched as an indicator of operator skill and experience.<sup>[12, 13]</sup>

It is a regulatory requirement in South Africa to (a) establish centre wide DRLs (or local DRLs, LDRLs) for identified procedures, (b) review them annually, and (c) contract a medical physicist to implement optimisation programmes for fluoroscopy and interventional radiology.<sup>[14]</sup> Several studies in the country have published LDRLs for adult fluoroscopy and fluoroscopy-guided (FGI) examinations<sup>[15, 16]</sup> as well as paediatric FGI.<sup>[17]</sup> However, there are no published reports that have proposed South African DRLs in paediatric fluoroscopy. Our study fills that gap by establishing LDRLs for fluoroscopic procedures at a specialist paediatric hospital.

#### **MATERIALS AND METHODS**

A retrospective single-centre study was conducted at the Red Cross War Memorial Hospital (RCWMH) from August 2020 to December 2021. RCWMH is a 272-bed specialist state paediatric hospital in South Africa and is affiliated with the University of Cape Town.

#### • Fluoroscopy unit

Fluoroscopic procedures at RCWMH are performed primarily on a Toshiba Ultimax-I, a C-arm system equipped with an integrated dose meter, high detective quantum efficiency (DQE) flat panel detector (FPD), ADRC, automatic brightness control (ABC), and software enhancements for dose reduction. At the conclusion of every procedure the system sends a summary of dose indices, including KAP), total FT, and  $K_{a,r}$ , to the facility's picture archiving and communications system (PACS).

#### • Dosimetry and quality assurance

The Toshiba Ultimax-i has an integrated dosimeter that measures KAP and K<sub>a,r</sub> at a reference point located 15 cm from the isocentre along the central beam axis towards the X-ray tube focus. The dosimeter was factory-calibrated; however routine tests of accuracy were performed at least annually by inspection bodies accredited by South African National Accreditation (SANAS) as required by regulations. <sup>[14]</sup> In addition, the authors independently verified the dosimeter calibration following the recommendations contained in the report of Task Group 190 of the American Association of Physicists in Medicine (AAPM).<sup>[18]</sup> In this manner, the accuracy of displayed KAP and K<sub>a,r</sub> values were found to be within 2% of values measured with an independent reference dosimeter.

#### • Data acquisition

At the end of every procedure, the fluoroscopy device displays the patient specific cumulative KAP,  $K_{a,r}$ , and total FT, which radiographers are required by regulations to capture at the console. In addition, the patient's age and weight are obtained from triage and included in the records.

For the period under investigation, the data were recorded manually and transferred to Microsoft Excel (Microsoft Corporation, Redmond, WA, United States). Records are thus accumulated and forwarded monthly to a medical physicist for analysis. At the time of writing this report, a centralised Digital Communication in Medicine (DICOM) export node was created to store radiation dose structured reports generated by the modality. For this study, data from fluoroscopic procedures that contributed at least 15% of the total workload over the data collection period. Data were retrieved retrospectively on consecutive patients and stratified into age and weight bands defined by Table 1.

#### Statistical analysis

Statistical analyses and creation of charts were performed with Microsoft Excel and Python (Python Software Foundation, Wilmington, DE, United States of America). The Pearson correlation test was used to evaluate the degree of correlation amongst the age, weight, KAP, K<sub>a,r</sub>, and FT.

#### **ETHICAL CONSIDERATIONS**

Approval to use patient data was obtained from the Univer-

 Table 1. Age and in parentheses, weight ranges recommended by ICRP 135<sup>[9]</sup>

Band 0 (5)		1 (15)	5 (30)	10 (50)	15 (80)	
Age range	0 to < 1 month	1 month to < 4 years	4 to < 10 years	10 to < 14 years	14 to < 18 years	
Weight range (kg)	< 5	5 to < 15	15 to < 30	30 to < 50	50 to < 80	



Figure 1. Frequency distribution of the paediatric fluoroscopy examinations during the study period.



**Figure 2.** Bar charts of age-stratified (A-1 to C-1), and weight stratified median dose indices (A-2 to C-2). KAP = kerma air product,  $K_{a,r}$  = air kerma at reference point, FT = fluoroscopy time.



**Figure 3.** Correlation matrix showing the degrees of correlation amongst age, weight, kerma air product, cumulative air kerma at reference point, and fluoroscopy time. The numbers inside the squares are the Pearson correlation coefficients calculated for each value pair. KAP = kerma air product,  $K_{a,r}$  = cumulative air kerma at reference point, FT = fluoroscopy time, WT = patient weight.

sity of Cape Town's Faculty of Health Sciences Human Research Ethics Committee (REF: 127/2022). Information that may be used to directly link specific patients to the data was removed in terms of patient privacy and confidentiality.

## RESULTS

A total of 685 fluoroscopy procedures were recorded over the period under investigation. The records of 79 procedures had incomplete or illegible dosimetric data and were excluded from the analysis. Procedures with at least 15 legible KAP,  $K_{a,r}$ , and FT entries were included. The frequency distribution is illustrated in Figure 1. Figure 2 shows bar charts of age- and weight-stratified median dosimetric indices from all cases included in the study. Figure 3 is a correlation matrix illustrating the degrees of correlation among the indices, age, and weight.

The most common fluoroscopic procedures over the period of investigation were barium swallow (BS, n=125), urodynamics (UD, n=93), modified swallow (MS, n=81), barium enema (BE, n=61), micturating cystourethrography (MCU, n=60), gastrostomy workup (GW, n=54), contrast via peg (CvP, n=21), and air reduction enema (EAR, n=17), accounting for at least 75% of the total workload.

A total of 597 records had legible age entries and were age-stratified; 448 records had legible weight entries and were weight-stratified. The age- and weight-stratified dose indices for all included procedures are given in Tables 1

and 2. Table 3 compares the results of selected procedures from this study with those found in the literature. In this report, the LDRL is defined at the 75<sup>th</sup> percentile of the dosimetric indices. Table 4 presents a comparison of the study's DRLs with those in the literature.<sup>[19-22]</sup>

### DISCUSSION

Over the period of review, examinations of the gastrointestinal tract formed the bulk of fluoroscopic procedures included in this report at 71%, followed by those of the urinary tract with 29% (see Figure 1). This result mirrors the report of the Image Gently initiative.[23] The relationships between age, weight, and median dose indices for all procedures, illustrated in Figure 2: A-1 and A-2, demonstrate a direct relationship between KAP and age, and KAP and weight, with the latter relationship being better defined. Fluoroscopic examinations of older or heavier children are associated with higher KAP values. Relationships between K<sub>a,r</sub> and age or weight are illustrated in Figure 2: B-1 and B-2. The relationships are direct until the age 10 and weight 50 kgs; where after reductions in K<sub>a,r</sub> are observed in the final age and weight bands. Figure 2: C-1 and C-2 suggest a negative correlation between FT and patient age or weight. This observation is confirmed in Figure 3 in which negative correlation coefficients were calculated and could well mean that clinicians encountered fewer complexities when examining older patients. Positive correlation coefficients among

		KAP (mGy.cm <sup>2</sup>				K <sub>a,r</sub> (mGy)				FT (min)			
Exam	Age Band	N	Median	25 <sup>th</sup> per- cen- tile	75 <sup>th</sup> per- cen- tile	N	Median	25 <sup>th</sup> per- cen- tile	75 <sup>th</sup> per- cen- tile	N	Median	25 <sup>th</sup> per- cen- tile	75 <sup>th</sup> per- cen- tile
	0	33	76	48	111	32	0.4	0.4	0.7	31	2.1	1.5	3.1
	1	63	191	112	294	62	0.7	0.3	1.1	62	2.9	1.9	3.9
BS	5	26	311	112	508	24	0.5	0.3	1.2	26	2.2	1.3	3.9
	10	16	526	402	846	15	1.2	0.7	1.8	17	1.8	1.4	3.0
	15	4	405	351	465	3	0.6	0.5	0.7	3	1.7	1.4	2.3
	1	28	55	33	110	28	0.1	0.06	0.2	28	0.5	0.2	1.1
	5	38	140	71	195	38	0.2	0.1	0.3	38	0.7	0.4	3.0
00	10	18	470	172	704	18	0.5	0.2	0.8	18	0.9	0.4	3.3
	15	11	346	271	543	11	0.4	0.3	0.5	11	0.6	0.5	2.0
	0	12	132	76	247	12	1.1	0.4	1.3	12	2.9	1.4	3.8
МС	5	72	163	89	300	72	0.7	0.4	1.2	70	2.9	1.8	3.3
IVIS	10	8	418	248	594	8	1.0	0.8	1.5	8	3.4	2.6	3.8
	15	4	190	136	874	4	0.4	0.3	1.5	4	2.1	1.1	2.7
BE	0	43	44	30	75	43	0.2	0.2	0.4	43	1.6	1.1	2.3
	5	19	48	28	99	19	0.3	0.1	0.4	19	1.5	1.1	2.5
	10	5	528	87	673	5	0.6	0.2	1.3	4	2.1	0.9	3.3
	0	5	74	73	110	5	0.6	0.3	0.6	4	2.5	2.1	3.5
DM	15	16	156	101	306	16	0.6	0.4	1.1	16	3.2	1.6	3.7
DIVI	10	4	303	261	411	4	0.6	0.6	0.8	4	1.6	1.1	2.0
	15	5	2080	1050	2141	6	2.4	2.0	2.7	6	3.7	3.0	4.1
	0	11	68	51	151	11	0.4	0.3	0.6	10	2.9	2.0	3.4
	1	29	148	94	273	29	0.5	0.3	1.0	29	2.4	1.6	2.9
MCU	5	15	424	200	665	15	0.7	0.5	1.5	15	1.9	1.5	3.0
	10	3	211	107	306	3	0.6	0.5	0.7	3	1.0	1.0	1.3
	15	4	613	466	1457	4	0.8	0.8	1.4	4	1.8	1.6	2.2
	0	13	79	46	131	12	0.3	0.2	0.4	13	1.6	1.0	2.5
CM	5	42	92	42	198	42	0.3	0.1	0.5	42	1.6	0.9	2.3
GW	10	4	472	326	760	4	1.0	0.8	1.9	4	2.6	1.7	3.9
	15	3	258	180	530	3	0.4	0.3	0.7	3	1.2	1.1	2.4
CVP	1	16	80	30	165	16	0.3	0.1	0.4	16	0.9	0.7	1.3
CVP	5	4	301	265	339	4	0.8	0.6	1.0	4	2.2	1.8	2.6
EAR	1	26	558	158	746	26	1.0	0.4	1.4	24	6.6	1.1	8.4

**Table 2.** Age-stratified radiation dose indices for barium swallow (BS), urodynamics, modified swallow (MS), barium enema (BE), barium meal (BM), micturating cystourethrogram (MCU), gastrostomy workup (GW), contrast via peg (CVP), and enema air reduction (EAR). KAP = kerma air product, K<sub>a,r</sub> = cumulative air kerma at reference point, FT = fluoroscopy time

**Table 3.** Weight-stratified radiation dose indices for barium swallow (BS), urodynamics, modified swallow (MS), barium enema (BE), barium meal (BM), micturating cystourethrogram (MCU), gastrostomy workup (GW), contrast via peg (CVP), and enema air reduction (EAR). KAP = kerma air product,  $K_{a,r}$  = cumulative air kerma at reference point, FT = fluoroscopy time

		KAP (mGy.cm <sup>2</sup>				K <sub>a,r</sub> (mGy)				FT (min)			
Exam	Weight Band	N	Median	25 <sup>th</sup> per- cen- tile	75 <sup>th</sup> per- cen- tile	N	Median	25 <sup>th</sup> per- cen- tile	75 <sup>th</sup> per- cen- tile	N	Median	25 <sup>th</sup> per- cen- tile	75 <sup>th</sup> per- cen- tile
	5	35	76	47	122	35	0.4	0.4	0.7	33	2.4	1.5	3.1
DC	15	49	199	112	298	49	0.7	0.3	1.0	49	2.8	1.8	3.7
63	30	32	432	240	689	32	0.7	0.3	1.5	32	2.9	1.5	1.2
	50	7	485	453	656	7	0.8	0.7	1.4	7	1.7	1.5	2.0
	15	31	84	30	138	31	0.2	0.1	0.3	31	0.8	0.3	1.2
ПР	30	41	147	70	273	41	0.2	0.1	0.3	41	0.6	0.4	1.1
00	50	13	436	292	628	13	0.4	0.3	0.7	13	0.8	0.4	0.9
	80	7	558	484	1005	7	0.5	0.4	0.9	7	0.5	0.3	1.4
MS	5	35	121	63	198	35	0.8	0.4	1.3	35	3.0	1.7	3.4
	15	40	182	130	370	40	0.7	0.4	1.4	40	3.0	2.5	3.6
	30	4	314	203	653	4	0.9	0.6	1.3	4	2.7	1.8	3.7
BE	5	46	40	30	70	46	0.3	0.2	0.4	46	1.5	1.1	2.4
	15	12	90	43	173	12	0.3	0.2	0.4	12	1.6	1.3	2.3
	5	7	74	63	141	7	0.6	0.2	0.6	7	0.1	0.1	0.1
BM	15	9	201	110	298	9	0.6	0.4	1.0	9	0.2	0.1	0.3
DIVI	30	5	317	288	575	5	0.6	0.5	1.7	5	0.3	0.3	0.6
	50	5	2080	1050	2141	5	2.1	1.9	2.6	5	2.1	1.1	2.1
	5	13	114	54	150	13	0.5	0.4	0.6	13	3	2.1	3.7
мсн	15	29	157	94	249	29	0.5	0.3	0.8	29	2.6	1.5	2.6
WICO	30	13	438	304	686	13	0.7	0.6	1.6	13	3.2	1.5	3.2
	50	6	449	404	678	6	0.8	0.7	0.9	6	1.8	1.4	1.8
GW	5	24	63	35	125	24	0.3	0.1	0.4	24	1.4	0.8	2.5
	15	23	106	63	207	23	0.3	0.2	0.5	23	1.6	1.0	2.0
	30	6	324	237	356	6	1.0	0.6	1.1	6	2.4	2.0	3.1
CVP	15	14	79	23	122	14	0.2	0.1	0.4	14	0.8	0.6	1.1
CVP	30	6	301	24	408	6	0.8	0.4	1.1	6	2.0	1.5	2.4
EAR	5	15	460	107	842	15	0.8	0.2	1.3	15	6.0	0.8	11.3

KAP and weight or age and  $K_{a,r}$  and weight or age were observed in keeping with Figure 2 and other reports from the literature.<sup>[24-26]</sup> These associations are well known and were the basis for recommendations by the ICRP to stratify DRLs by weight, or age in cases where weight data is unavailable.<sup>[9]</sup> The results in Figure 3 also suggest a strong positive correlation between patient age and weight in keeping with ICRP 135.<sup>[9]</sup>

Much of the DRL data currently available in the literature is age-stratified, for that reason our results are stratified both in age (Table 2) and weight (Table 3) for comparison with existing data. Table 4 presents a comparison of KAP LDRLs from this study with results from highly cited studies in the literature for selected procedures. Our reference levels for barium swallow were lower than those of Hart and Shrimpton,<sup>[20]</sup> but higher than the 2005 study by Hiorns et al.<sup>[21]</sup> The DRLs for barium meal are comparable to those of Hart and Shrimpton,<sup>[20]</sup> but higher than the results of Hiorns et al.<sup>[21]</sup> Finally, MCU dose values from this study are lower than results from the 2018 European guidelines.<sup>[19]</sup> In general, our dose values did not differ significantly from reference data in the literature, showing that our practices are on par with international standards.

Age Band	Weight Band	Exam	LDRL This study (mGy cm²)	DRL 2018 EU DRLs <sup>[19]</sup> (mGy cm <sup>2</sup> )	DRL 2010 EK study <sup>[20]</sup> (mGy cm <sup>2</sup> )	Hiorns et al. 2005 <sup>[21]</sup> (mGy cm²)	NRPB 2000 <sup>[22]</sup> (mGy cm <sup>2</sup> )
0			111		210	80	
1			294		390	80	
5		Barium swallow	508		460	120	
10			846		1800	320	
15			465		3000	320	
0		Barium Meal	110		130	80	
1			-		210	80	
5			306		240	120	
10			411		650	320	
15			2141		2000	320	
0			151			50	400
1			273			50	900
5		Micturating Cys-	665			100	1100
10		tourethiography	306			420	2100
15			1457			420	470
	5	Micturating Cys- tourethrography	150	300			
	15		249	700			
	30		686	800			
	50		678	750			

 Table 4. A comparison of diagnostic reference levels of selected fluoroscopic studies in this study and reference levels from the literature.

 LDRL = local diagnostic reference level, DRL = diagnostic reference level, NRPB = National Radiological Protection Board

## LIMITATIONS

The results of several important fluoroscopic examinations were excluded from the study owing to illegible data arising from manual data capturing. At the time of writing this report, a Radiation Dose Monitoring system had been installed to autonomously capture radiation dose structured reports at the modality for archiving and analysis. We strongly recommend that other centres do likewise.

## CONCLUSION

Establishment of diagnostic reference levels for fluoroscopic procedures at local, regional, and national levels is recommended for dose comparison and optimisation. Local DRLs

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for selected procedures have been established at a dedicated paediatric hospital and compare well with references in the literature. This study is an initial step towards establishing South African national DRLs in paediatric fluoroscopy.

#### **CONFLICT OF INTEREST**

We report no potential conflicts of interest.

#### **AUTHORS' CONTRIBUTION**

JM was the main researcher; TP and JM were responsible for data collection; TP assisted with interpretation of the results; JM drafted the manuscript.

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