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Establishment and utilization of diagnostic reference level for interventional procedures for adult patients in Ghana

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Abstract

Purpose In recent years various international organisations including IAEA, ICRP, and EURATOM consider interventional radiology procedures to be special practice, involving high doses of radiation with considerable potential risk associated with these procedures. The objective of this study is to assess dose to patients undergoing interventional procedures in five diagnostic facilities, leading to the establishment and utilization of Diagnostic Reference Levels in interventional procedures in Ghana.

Methods A sample of 748 procedures performed in five hospitals in Ghana were collected. Hospitals were asked to complete a questionnaire giving information on procedure, equipment, and protocol, experience of operator graded in number of procedures performed, and complexity level of each procedure. The procedures type included percutaneous nephrostomy, Intraforaminal infiltration, catheter embolization, percutaneous liver drainage, intracranial circulation, intraoperative angiography, biopsy, abdominal aorta endoprosthesis, splenic angiography, biliary stenting. For each procedure, fluoroscopy time, incident air-kerma at the Interventional Reference Point (IRP), number of images (frame), kerma-area product (KAP) Fluoro and Total kerma-area product, together with total irradiation time were collected. The upper quartile of the median distribution for number of images, fluoroscopy time, total KAP, and KAP Fluoro were used as measure of DRL.

Results The study results shows that the proposed DRL dose metric ranged from a minimum of 1.8 Gy.cm and 5.51 Gy. cm for Percutaneous Liver Drainage to a maximum of 86.98 and 118.80 for Abdominal Aorta Endoprosthesis in terms of KAP Fluoro and Total KAP respectively. The study also observed that the abdominal aorta endoprosthesis procedures took a longer time with significant number of images to performed relative to other cases. Time for abdominal aorta endoprosthesis procedures took respectively as much as three-fold comparable to the period needed for Intraforaminal infiltration, with more images acquired in the same procedures. The effect of this longer length of time and more image acquired resulted in higher patients' radiation dose, in terms of KAP Fluoro and total KAP, as applied to abdominal aorta endoprosthesis than any other procedures. The DRLs were found to be strongly influenced by clinical circumstances like complexity of the procedure, the length of time, training and experience of the operator. Furthermore, it was also observed that, the quality of the images for each procedure had direct positive correlation with estimated patient dose values.

Conclusion The preliminary results of this study propose local DRLs for the selected procedures, setting a good basis for establishment of a national DRL for interventional procedures in Ghana. The proposed DRL values are comparable to international published data from Spain, US and Switzerland.

Keywords Interventional procedure · Fluoroscopy · Diagnostic reference level · Fluoroscopy time · Kerma-area product

1 Introduction

In 1996, the International Commission on Radiological Protection (ICRP) first introduced the term 'diagnostic reference level' (DRL) in *Publication 73* [1]. The concept

was subsequently developed further, and practical guidance was provided in 2001. After few years of its implementation, DRLs have been proven to be an effective tool for optimisation of radiation protection in the medical exposure of patients for diagnostic and interventional procedures. The principles of justification and optimisation

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of protection are key and complementary radiological safety tenets in radiation medicine. In recent times, DRL has been used to aid in optimisation of radiation protection in medical exposure of patients for diagnostic and interventional procedures. A DRL value is a selected level of a radiation dose quantity (DRL quantity) for broadly defined types of equipment for typical examinations for groups of standard-sized patients or, in certain specific circumstances, a standard phantom. DRLs do not apply to individual patients [2]. They are derived from an arbitrary threshold in a distribution of values obtained locally and collected nationally or regionally.

Additionally, DRL is a supplement to professional judgement and does not provide a dividing line between good and bad medical practice. All individuals who have a role in subjecting a patient to a medical exposure should be familiar with DRLs as a tool for optimisation of protection. It is however, important to point out that, the application of DRLs may not be sufficient, by itself, for optimisation of radiation protection. A DRL is generally determined as the 75th percentile level of the measured or surveyed radiation dose distribution. It can be applied in various diagnostic procedures, such as computed tomography (CT), nuclear medicine, and interventional radiology [3].

Optimisation is generally concerned with maintaining the quality of the diagnostic information provided by the examination commensurate with the medical purpose while, at the same time, seeking to reduce patient exposures to radiation to a level As low As Reasonably Achievable (ALARA principle). Image quality or, more generally, the diagnostic information provided by the examination (including the effects of post-processing), must also be evaluated. Methods to achieve optimisation that encompass both DRLs and image quality evaluation should be implemented. In some cases, optimisation may result in an increase in dose. Compliance with DRLs does not, by itself, indicate that the procedure is performed at an optimised level with regard to the amount of radiation used. Therefore, the ICRP recognises that additional improvement can often be obtained by using the median value (the 50th percentile) of the distribution of values of dose-related quantities used to set the national or regional DRL value, rather than the mean value that was commonly used for the DRL value. The median value of the distribution also provides guidance on when investigation of image quality should be considered as a priority.

The ICRP, in 2007, recommended the introduction of DRL for interventional procedures [3]: their introduction and use in clinical practice has contributed and will continue to contribute to raising the level of optimization of radiological techniques. When the interventions are long and complex, the radiation dose to the patient could exceed the threshold and recommendations of various organisations in radiation protection leading to possible tissue reactions [3].

4]. Additionally, this may lead to some effect on patient's skin receiving highest dose, with potential undesirable effects. The threshold value for the first reaction of the skin, erythema, is 2 Gy [5]. As far as concerns effects on the crystalline lens (cataract), the ICRP has set an induction threshold of 0.5 Gy. Lens opacities and cataracts may be induced during neurointervention procedures [3].

As part of patient's protection, various international organisations including IAEA, ICRP, and EURATOM consider interventional radiology procedures to be special practice, involving high doses of radiation. Important directive on the health protection of Individuals in relation to medical exposures by European council of ministers on 30 June 1997 (MED) (97/43/EURATOM) [6]. This was to complements the Basic Safety Standards Directive of 1996 (96/29/EURATOM) as regards medical exposures, which comes into force at the same date. The directive aimed to optimize diagnostic efficacy at reasonable dose to the patient and to reduce the number of unnecessary and inadequate exposures. One such measures was the recommended use of DRL as part of the guidelines for Advisory Data Set for its clinical application [7].

The ICRP Publication 135 [8] on DRL for interventional procedures, states that DRL values for x-ray procedures are often set, arbitrarily but reasonably, at the 75th percentile of the median distribution of quantity including kerma-area product (KAP), fluoroscopy time (FT) and cumulative or total Fluoro kerma-Area product (Ka,r) at the Interventional Reference Point - IRP). The purpose of a DRL is to identify facilities in which investigation of practices is advisable because protection is not optimized (i.e., where the local median value of the DRL is higher than the national or regional DRL) [7]. If median values are higher than DRL values, the investigation should start with the evaluation of the equipment, the evaluation of procedure protocols, and also the evaluation of operator's technique. Higher values can be justified by considering the complexity of the procedure. However, even at lower DRL values, improvements may still be possible.

Generally, local surveys of DRL quantities are normally carried out as part of the clinical audit for medical imaging procedure including diagnostic and interventional procedure. Based on the recommendation of ICRP Publication 135, a representative selection of examinations for each x-ray unit should be surveyed at intervals of about three years, and when substantial changes in technology or software have been introduced. The factors involved in establishing DRL include, survey methodology, equipment performance, procedure protocol, operator skill and, for interventional techniques, procedure complexity [3].

Furthermore, the most important component of establishing DRL is establishing a specific responsibility of the various professionals and organisations involve in medical



Fig. 1 Philip (Azurion 7 F20, M20 and C20) CathLab machines

imaging process. The team of professionals including Medical Physicist, Radiologist and the Radiography, and organisations include the regulatory authority, ministry of health and the professional bodies. In Ghana training of these three professionals are extremely comprehensive making them extremely skillful for any task assigned to them in the process of establishing DRL. For instance, medical physicist training is an 8-year training programme with 4-year basic BSc in physics and related programme, while the training of Radiography is a 4-year BSc training in Radiography. Furthermore, the training of Radiologist is a specialized 4-year training after 6 years of MBCHB certification. Collaboration of these professionals in establishing DRL in Ghana has been cooperative and involving. Since 2020, the team has been involved in establishing DRL in four modalities including CT, SPECT, interventional radiology and Digital Radiography [8, 9].

The aim of this study was to establish and propose DRL values of nine most common interventional procedures of adult patients in terms of the kerma-area product (KAP), KAP fluorography and fluoroscopy time (FT) in Ghana. The upper

quartile of the median values of the distributions were compared to published DRL values as suggested by ICRP 135.

2 Materials

The materials used for the study include 3 Philip (Azurion 7 F20, M20 and C20), 1 Siemen Artis zee with PURE and 1 Canon Alphenix. Five (5) radiology centres included 4 from Government of Ghana facilities and 1 private facility all in Accra. All the facilities had picture archiving and communication (PAC) system with additional well-functioning radiology departments information systems for managing the imaging and interventional process and the data systems. Initially, quality control (QC) assessments were performed on all the machines. The 5 CATLAB Machines that were used were manufactured between 2020 and 2023 and installed in the radiology centres between 2021 and 2023. Figure 1. Represent 3 Philip (Azurion 7 F20, M20 and C20), CATLAB, Fig. 2 is the 1 Siemen Artis zee with PURE machine and Fig. 3 is the Canon Alphenix CATLAB machine. Details of the various machines are described below.

Fig. 2 Siemen Artis zee with PURE Cathlab machine



Fig. 3 Canon Alphenix Cath-Lab machine



3 Equipment description

3 Philip Azurion 7 F20, M20 and C20 with latest state of the art, single plane ceiling mounted C-arm / G-arm Cardiovascular Angiography system with flat detector technology digital imaging system for diagnostic procedures and interventional cardiovascular procedures, valvuloplasty and vascular Angiography, DSA and cardiovascular electrophysiology. The Philip system have the following features: A motorized with C-Arm angulations of minimum RAO/ LAO + 110 degrees CARN/CAUD + 45 degrees. At head end position. With 20 deg/sec or more speed for LAO/RAO AND 15 deg/sec or more speed for CARN / CAUD with 3D Acquisition reconstruction and visualization in real time of volume in volume rendering technique (VRT) and a possibility of acquiring 3D Coronary Arteriography package along with the stent enhancement package.

3.1 1 Siemen Artis zee with PURE

The Artis zee product family offers a comprehensive portfolio and complete range of applications to increase your clinical capabilities and ease your workflow in Interventional Cardiology, Interventional Radiology and Surgery. The Artis's zee offers high-end applications for surgery through real time 3D imaging, high frame rates, and excellent image quality at low dose. The Artis zee high-end imaging systems enable image-guided therapy that cannot be achieved with other solutions in an OR environment today.

3.2 1 Canon Alphenix

The Canon Alphenix is new flagship platform of systems incorporates all-new features that enable clinicians to deliver images with clarity and precision without compromising workflow and while prioritizing low dose. The Canon Alphenix is the world's first high-definition detector with 76 micron resolution for resolving fine details, the hybrid 12×12 -inch panel is combined with high-definition flat panel technology

that results in resolutions of 2.6 lp/mm (Standard) and 6.6 lp/mm (Hi-Def Detector). The Alphenix Hi-Def Detector technology helps clinicians see finer details during complex interventional procedures such as stent positioning and stent apposition, wire and catheter navigation through the stent struts, and observation of coil deployment. The new Alphenix Hi-Def Detector have the following new features: Nextgeneration Illuvis technology reduce image noise with less lag time, and provide clearer images at steep angles while delivering a decreased frame rate that can help reduce dose; Real-Time Auto-Pixel Shift to automatically correct misalignment between the contrast image and mask image during digital subtraction angiography and 2-D road mapping utilization; and Tablet touch-screen to optimize tableside workflow with simplified control functions and the option to assign "favorites" to customize the interface, per physician.

4 Quality control procedure

The quality control (QC) assessment of the equipment were performed using IEAE Handbook of basic QC Test for Diagnostic Radiology [10]. The equipment used for the quality control procedure include RTI Piranha for kVp, dose and dose rate assessment, PMMA slabs of $30 \times 30 \times 20$ cm, High contrast resolution test tool, Low contrast resolution test tool, Copper filters of 1, 2 and 4 mm and Beam alignment test tool. Before accepting and recording the dose report values, two verification processes were done for accuracy and consistency.

First the accuracy and consistency of the measured QC values and secondly the comparison of the QC values as against the displayed values and the dose report. For accuracy and consistency of the displayed Incident Air-Kerma and Kerma-Area Product values, fluoroscopy time and number of radiographic images were determined based on manufacturers recommendation of the measured value at acceptance and commissioning test should not varied more than 15%.

Secondly, the recorded values were independently checked with the piranha and compared with the displayed values from the console and the dose report.

5 Methods

A retrospective study was conducted by collecting data from procedures performed in the period between October 2022 and October 2023 in five diagnostic centres/hospitals in Ghana. The data were retrieved from dose reports of the Picture Archiving and Communication System (PACS) by the research team based a structured form that was designed and distributed among the five participating facilities. The data collected include the displayed Incident Air-Kerma and Kerma-Area Product values, fluoroscopy time and number of radiographic images of at least 30 patients for diagnostic fluoroscopy and 50 patients for FGI procedures based on ICRP Publication 135 recommendations. Patient radiation exposure was evaluated using the displayed Incident Air-Kerma and Kerma-Area Product values, which were used to estimate KAP Fluoro and Total KAP. These were used to establish diagnostic reference level in fluoroscopy guided interventional procedures in Ghana.

A total of 748 sample procedures from the dose reports that met the selection criteria were retrieved. This involved the collection of data from 9 angiography procedures including Biliary stent positioning (76 patients), Splenic angiography (83 patients), Abdominal aorta endoprosthesis (66 patients), Biopsy (77), Intracranial circulation (94 patients), Percutaneous liver drainage (63 patients), Catheter embolization (84 patients), Intraforaminal infiltration (118 patients), and Percutaneous nephrostomy (87 patients). For each procedure, number of images (or frames), fluoroscopy time, air kerma-area product and air kerma at the IRP were collected from which total KAP (mGy·cm²) and KAP fluorography (mGy·cm²) were estimated. The minimum, maximum, mean, median, lower and upper quartile values were tabulated and analyzed. The upper quartile values of each facility median values were used as metric for the proposed preliminary DRL in Ghana, based on ICRP publication 135 recommendation.

Inclusive criteria were adult patients of age 18 years and above with complete dose information for assessment. In addition to the availability of patient biodata including standard weight of 70-100 kg. Patients without this information were excluded from this study. Finally, data from the DICOM header was retrieved and analysed together with all the associated images.

6 Image quality assessment

As part of the retrospective analysis of the data of this study, both the data from the DICOM header and the images were retrieved and used for the analysis. A qualitative image quality assessment was used as part of the assessment process. These were based on the acceptance of the quality of images produced per each interventional procedure as indicated on the patient report. Which were accepted for interventional process for clinical application.

7 Results and discussion

There were two verification processes for quality control assessment; the accuracy and consistency of the measured QC values and secondly the comparison of the QC values as against the displayed values and the dose report were consistent.

First the accuracy and consistency of the displayed Incident Air-Kerma and Kerma-Area Product values, fluoroscopy time and number of radiographic images were determined based on manufacturers recommendation of the measured value at acceptance and commissioning test were less than 15%. Additionally, this was also in agreement with IAEA Harmonized Diagnostic Radiology Quality Control Programme recommendation. Based on the IAEA Handbook on Basic Quality Control Tests for Diagnostic Radiology, IAEA Human Health Series No. 47 (2023) [10].

Secondly, the recorded values were compared with the displayed values from the console and the dose report. However, there were no variation between the displayed values and the measured values throughout the study.

Table 1 presents data on the interventional radiology procedures. Data was compiled using statistical metrics of minimum, 25th percentile, mean, median, 75th percentile and maximum. Within the study period, intraforaminal infiltration procedures are observed to dominate the interventional procedures performed. These techniques have been mostly employed in the evaluation and management of conditions such as herniated discs, spinal stenosis, or nerve impingement. The procedure is often performed as a diagnostic or therapeutic intervention to address pain and inflammation associated with nerve roots exiting the spinal cord. Averagely, abdominal aorta endoprosthesis procedures took much longer time to perform relative to the other conditions. Time taken for aorta abdominal endoprosthesis procedure could be as much as three-fold the period needed for intraforaminal infiltration, while more images are acquired in intracranial circulation procedures. More radiation dose, in terms of KAP fluoro and total KAP, was observed in the case of Abdominal Aorta Endoprosthesis than the other procedures.

Diagnostic reference levels serve as benchmarks to optimize and monitor radiation doses in medical imaging procedures and to reduce wide discrepancies in the application of procedures. From the data retrieved, very wide variations were observed in some cases of the same type of examination. While this may raise a concern of inconsistency, several
 Table 1
 Data from angiographic interventional procedures

Procedure	No. of patients	Metric	Frame (fps)	Fluoro time(mins)	KAP Fluoro (Gy·cm ²)	Total KAP (Gy·cm ²)
Biliary Stent Positioning	76	Minimum	1	0.08	0.06	0.06
		25th Percentile	2	0.62	1.32	3.42
		Mean \pm SD	6	8.28	41.66	59.88
		Median	5	3.57	5.05	13.43
		75th Percentile	8	12.23	42.07	68.40
		Maximum	25	56.75	359.09	435.92
Splenic Angiography	83	Minimum	1	0.03	0.01	0.21
		25th Percentile	3	4.30	0.56	7.32
		Mean \pm SD	7	11.60	64.22	91.27
		Median	5	8.48	13.35	37.85
		75th Percentile	10	17.53	72.29	115.40
		Maximum	24	66.57	729.17	815.19
Abdominal Aorta Endoprosthesis	66	Minimum	2	0.12	1.59	2.05
•		25th Percentile	7	8.07	26.01	48.17
		$Mean \pm SD$	11	16.38	106.48	140.29
		Median	9	14.32	85.49	108.65
		75th Percentile	14	23.02	141.05	198.06
		Maximum	25	72.13	734.17	835.17
Biopsy	77	Minimum	1	0.08	1.40	1.74
1.5		25th Percentile	6	5.33	19.81	29.05
		Mean + SD	11	14.48	105.94	135.58
		Median	8	11.86	49.54	73.12
		75th Percentile	14	20.42	115.50	195.03
		Maximum	48	69.45	742.46	837.45
Intracranial Circulation	94	Minimum	1	0.98	0.31	0.31
		25th Percentile	7	5.67	32.24	39.92
		Mean + SD	12	14 23	66.67	84 23
		Median	9	10.00	50.80	63.85
		75th Percentile	15	20.52	84.95	111.83
		Maximum	38	78.32	263 37	345 36
Percutaneous Liver Drainage	63	Minimum	1	0.03	0.06	0.06
Terentaneous Liver Dramage	05	25th Percentile	1	1.08	0.89	1.51
		Mean + SD	1	4 78	2.94	17.29
		Median	3	2.10	1 74	5 463
		75th Percentile	5	4 52	2.28	13.68
		Maximum	12	30.55	18.45	112.34
Catheter Embolization	84	Minimum	12	0.28	0.71	2.05
Catheter Embolization	04	25th Percentile	6	6.82	0.71 26.41	35.80
		Mean + SD	11	15.40	104.27	137.05
		Median	0	11.10	64.66	02.07
		75th Dercontile	9	20.52	110 172	92.07
		/Jui Percentile	13	20.33	700.46	130.41
Introforominal Infiltration	110	Minimum	39	49.13	0.00	932.09
muatorammar mintration	110	Nillinnulli	1	0.29	0.99	0.99
		Zour Percentile	э 5	2.20	J.19 15 97	9.08
		Medior Medior	3	4.33	13.8/	21./ð
		75th Dana and 1	4 5	5.12	12.01	13.37
		/ Sui Percentile	J 14	5.50 20.55	23.3U	JU.//
		Maximum	14	20.55	38.17	92.88

Procedure	No. of patients	Metric	Frame (fps)	Fluoro time(mins)	KAP Fluoro (Gy·cm ²)	Total KAF (Gy·cm ²)
Percutaneous Nephrostomy	87	Minimum	1	0.26	0.57	0.57
		25th Percentile	3	2.27	1.33	6.26
		$Mean \pm SD$	7	10.40	44.22	68.79
		Median	5	4.58	5.60	18.25
		75th Percentile	9	11.75	41.56	86.95
		Maximum	39	59.27	790.46	932.69

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factors could be attributed to be the cause. The size and body composition of patients can affect the absorption and attenuation of X-rays, thus influencing the required radiation dose. Adult patients may have different size and weight resulting in different dose parameters. The clinical indications for interventional procedure can vary widely, and the complexity of the procedure may influence the radiation dose administered.

Differences in interventional systems may also have varying technical specifications and capabilities and impact on the duration and extent of the medical procedure. The age and model of the equipment, as well as the presence of advanced imaging technologies like flatpanel detectors and dose modulation can impact dose levels. The differences in imaging protocols and techniques used, based on clinical requirements and complexity of the angiographic procedures, also influenced differences in radiation dose delivered. Largely, variations in the training and practices of the healthcare professionals, i.e., interventional radiologists and technologists, influence the use of imaging equipment and the application of protocols, impacting the dose levels.

Finally, a higher radiation dose quantity, in terms of KAP Fluoro and total KAP, in the case of Abdominal Aorta Endoprosthesis was also observed than all other procedures. In conclusion it was observed that, the study results were comparable to other regional and international studies. In addition, it was also observed that, the time taken for each procedure to complete had direct positive correlation with estimated patient dose values. That is, the higher the time taken for a procedure to be completed, the higher the dose values in terms of the displayed Incident Air-Kerma and Kerma-Area Product values, with corresponding higher KAP Fluoro ($Gy \cdot cm^2$) and Total KAP ($Gy \cdot cm^2$) recorded and hence the higher the potential risk to patients and staff.

Furthermore, it was also observed that, the quality of the images for each procedure had direct positive correlation with estimated patient dose values. However, all the images used met the basic acceptance criterion as they were good enough for both FGI and diagnostic procedures. Additionally, it was observed that most of the procedure used were optimised as the patient dose and the quality of the imaging were all within the clinical accepted range. This was also confirmed with the fact that all the images access were accepted with their corresponding structured dose reports and classified as good quality for clinical application by the interventional radiologist.

Based on ICRP publication 135, the median values for each machine at each of the five facilities were estimated, then the 3rd quartile values were estimated to represent the proposed DRL of the country. Tables 2, 3, 4, 5, 6, 7, 8, 9 and 10 represent the median values distribution for the five facilities of each procedure based on which the upper quartile of the median distribution of the various procedures were estimated. Tables 2, 3, 4, 5, 6, 7, 8, 9 and 10 is intended to aid interinstitutional comparison.

Table 2 summarizes the Biliary Stent Positioning procedure of the five facilities and represent the 3rd quartile

Table 2 Biliary stentpositioning procedure

Procedure	No. of images	Fluoro time(mins)	KAP Fluoro (Gy•cm ²)	Total KAP (Gy·cm ²)
Biliary Stent Positioning 1	6	3.57	4.98	12.54
Biliary Stent Positioning 2	5	3.55	5.05	13.43
Biliary Stent Positioning 3	6	3.88	5.16	12.94
Biliary Stent Positioning 4	4	3.58	5.05	13.43
Biliary Stent Positioning 5	4	3.53	5.05	13.43
Upper Quartile (Proposed DRL)	6	3.73	5.11	13.43

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the DRE of the Dropsy procedure in terms	estin
images, Fluoro time (mins), KAP Fluoro	the n
Total KAP (Gy⋅cm ²).	nal I

estimates of the median values distribution. The table present the median distribution as the DRL of the Biliary Stent Positioning procedure in terms of number of images, Fluoro time (mins), KAP Fluoro (Gy·cm²) and Total KAP (Gy·cm²).

Table 3 summarizes the Splenic Angiography procedure of the five facilities and represent the 3rd quartile estimates of the median values distribution. The table present the median distribution as the DRL of the Splenic Angiography procedure in terms of number of images, Fluoro time (mins), KAP Fluoro (Gy·cm²) and Total KAP $(Gv \cdot cm^2)$.

Table 4 summarizes the Abdominal Aorta procedure of the five facilities and represent the 3rd quartile estimates of the median values distribution. The table present the median distribution as the DRL of the Abdominal Aorta procedure in terms of number of images, Fluoro time (mins), KAP Fluoro (Gy·cm²) and Total KAP ($Gy \cdot cm^2$).

Table 5 summarizes the Biopsy procedures of the five facilities and represent the 3rd quartile estimates of the median values distribution. The table present the median distributi e in terms of numbe $(Gy \cdot cm^2)$

Table 6 summarizes the Intracranial Circulation procedure of the five facilities and represent the 3rd quartile estimates of the median values distribution. The table present the median distribution as the DRL of the Intracranial Circulation procedure in terms of number of images, Fluoro time (mins), KAP Fluoro (Gy·cm²) and Total KAP $(Gy \cdot cm^2)$.

> Table 7 summarizes the Percutaneous Liver Drainage procedure of the five facilities and represent the 3rd quartile estimates of the median values distribution. The table present the median distribution as the DRL of the Percutaneous Liver Drainage procedure in terms of number of images, Fluoro time (mins), KAP Fluoro (Gy·cm²) and Total KAP $(Gy \cdot cm^2)$.

> Table 8 summarizes the Catheter Embolization procedure of the five facilities and represent the 3rd quartile estimates of the median values distribution. estimates of the median values distribution. The table present the median distribution as the DRL of the Catheter Embolization procedure in terms of number of images, Fluoro time (mins), KAP Fluoro (Gy·cm²) and Total KAP $(Gy \cdot cm^2)$.

> Table 9 Summarizes the Intraforaminal Infiltration procedure of the five facilities and represent the 3rd quartile estimates of the median distribution. The table present nedian distribution as the DRL of the Intraforaminfiltration procedure in terms of number of images,

Table 5	Bionsy	procedure
Table J	DIODSY	procedure

Procedure	No. of images	Fluoro time(mins)	KAP Fluoro (Gy•cm²)	Total KAP (Gy·cm ²)
Biopsy 1	9	13.57	50.59	78.19
Biopsy 2	8	11.75	49.54	73.13
Biopsy 3	8	11.98	52.49	72.23
Biopsy 4	7	11.87	49.54	73.12
Biopsy 5	8	11.55	49.53	73.11
Upper Quartile (Proposed DRL)	8.5	12.76	51.54	75.66

on as the DRL of the Biopsy procedur
er of images, Fluoro time (mins), KA
and Total KAP ($Gy \cdot cm^2$).

Splenic 5 8.48 13.35 Angiography 3 Splenic 8.50 13.35 4 Angiography 4 8.32 Splenic 5 13.34 Angiography 5 5 8.51 13.37 **Upper Quartile** (Proposed DRL)

Table 3 Splenic angiography procedure

No. of

images

5

5

Fluoro

8.17

8.52

time(mins)

KAP

13.39

13.34

Fluoro (Gy·cm²) Total KAP (Gy·cm²)

36.90

37.85

37.86

37.85

37.85

37.85

Procedure

Splenic

Splenic

Angiography 1

Angiography 2

Table 4 Abdominal aorta procedure

Procedure	No. of images	Fluoro time(mins)	KAP Fluoro (Gy·cm ²)	Total KAP (Gy·cm ²)
Abdominal Aorta Endoprosthesis 1	10	15.35	87.46	119.65
Abdominal Aorta Endoprosthesis 2	9	14.25	85.49	108.65
Abdominal Aorta Endoprosthesis 3	9	14.33	86.50	117.95
Abdominal Aorta Endoprosthesis 4	8	14.18	85.49	108.65
Abdominal Aorta Endoprosthesis 5	8	14.31	85.49	108.65
Upper Quartile (Proposed DRL)	9.5	14.84	86.98	118.80

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 Table 6
 Intracranial circulation

 procedure
 Procedure

Procedure	No. of images	Fluoro time(mins)	KAP Fluoro (Gy·cm ²)	Total KAP (Gy⋅cm ²)
Intracranial Circulation 1	9	10.17	51.79	62752
Intracranial Circulation 2	9	9.93	50.80	63853
Intracranial Circulation 3	9	10.00	50.81	63852
Intracranial Circulation 4	8	10.03	50.80	63853
Intracranial Circulation 5	9	9.90	50.79	63849
Upper Quartile (Proposed DRL)	9	10.10	51.30	63853

Table 7 Percutaneous liverdrainage procedure

Procedure	No. of images	Fluoro time(mins)	KAP Fluoro (Gy·cm ²)	Total KAP (Gy·cm ²)
Percutaneous Liver Drainage 1	4	2.18	1.85	5.56
Percutaneous Liver Drainage 2	3	2.05	1.73	5.47
Percutaneous Liver Drainage 3	3	2.10	1.74	5.46
Percutaneous Liver Drainage 4	3	2.20	1.74	5.46
Percutaneous Liver Drainage 5	3	2.08	1.74	5.46
Upper Quartile (Proposed DRL)	3.5	2.19	1.80	5.51

Procedure	No. of images	Fluoro time(mins)	KAP Fluoro (Gy·cm ²)	Total KAP (Gy·cm ²)
Catheter Embolization 1	9	9.98	63.72	91.08
Catheter Embolization 2	9	10.98	64.66	92.07
Catheter Embolization 3	9	11.13	64.66	92.07
Catheter Embolization 4	9	11.20	64.67	92.17
Catheter Embolization 5	9	11.12	64.66	92.07
Upper Quartile (Proposed DRL)	9	11.17	64.67	92.12

Fluoro time (mins), KAP Fluoro ($Gy \cdot cm^2$) and Total KAP ($Gy \cdot cm^2$).

Table 10 Summarizes the Percutaneous Nephrostomy procedure of the five facilities and represent the 3rd quartile estimates of the median distribution. The table present the median distribution as the DRL of the Percutaneous Nephrostomy procedure in terms of number of images, Fluoro time (mins), KAP Fluoro ($Gy \cdot cm^2$) and Total KAP ($Gy \cdot cm^2$).

Based on ICRP 135 recommendation, median estimates of the dose descriptors (number of images, fluoro time, KAP fluoro and total KAP), is used as the metric for the proposed

Table 9	Intraforaminal
infiltrati	on procedure

Procedure	No. of images	Fluoro time(m)	KAP Fluoro (Gy·cm ²)	Total KAP (Gy·cm ²)
Intraforaminal Infiltration 1	4	3.85	12.81	15.30
Intraforaminal Infiltration 2	5	3.67	13.11	15.37
Intraforaminal Infiltration 3	4	3.72	12.01	15.37
Intraforaminal Infiltration 4	4	3.77	12.00	15.68
Intraforaminal Infiltration 5	5	3.68	12.01	15.11
Upper Quartile (Proposed DRL)	5	3.81	12.96	15.52

Table 10Percutaneousnephrostomy procedure

Procedure	No. of images	Fluoro time(mins)	KAP Fluoro (Gy·cm ²)	Total KAP (Gy·cm ²)
Percutaneous Nephrostomy 1	5	4.85	5.69	19.35
Percutaneous Nephrostomy 2	5	4.58	5.59	18.25
Percutaneous Nephrostomy 3	5	4.59	5.60	18.25
Percutaneous Nephrostomy 4	5	4.52	5.61	18.26
Percutaneous Nephrostomy 5	5	4.57	5.60	18.25
Upper Quartile (Proposed DRL)	5	4.72	5.62	18.81

DRLs, as presented in Table 11. The proposed DRL of each procedure as presented in Table 11 were made available to the various facility and the regulatory authority for clinical application. The LDRL were comparable within the various facilities with a variation of less than recommended 5%.

8 Comparison with international published data

When comparing the DRL for the local KAP with the average values of the other countries as presented in Table 12, it was found to be as low as 20% to 30% to to the average values of the other countries. In addition, when comparing the local DRL for the fluoroscopy time with the average of the other countries, the local DRL was lower, in all the procedures, which were at similar levels. Details of published measured values for Switzerland, Spain and United States are shown in Table 12. Furthermore, the median KAP values ranged from 12 to 1215 Gy.cm² [11–14].

In comparison with published data, the median KAP values in this study were within reported ranges for all the

procedure. However, the results of the estimated values were far smaller than published data, for instance, the median Biliary stent KAP was estimated to be 13.43 Gy. cm² which is comparable smaller compared to 240 Gy.cm² DRL established in Switzerland, 100 Gy.cm² in USA and 80 Gy.cm² established in Spain. Additionally, the established DRL of the percutaneous interventional procedures ranged between 2 to 20 Gy.cm² in this study, which was comparatively similar percutaneous procedures in Switzerland, with estimated values ranged from 110 to 260 Gy. cm². Furthermore, the various interventional embolization procedure estimated in this study was 92 Gy.cm², this was comparable smaller to 240 to 390 Gy.cm² in US; 160 to 800 in Switzerland and 236 Gy.cm² in Spain [11].

In terms of Fluoroscopy time, the various interventional procedures were higher than the estimated values in this study. For instances, the longest procedure in this study was 15 min in Abdominal Aorta Endoprosthesis procedure, while the shortest procedure was 2 min in Percutaneous Liver Drainage procedure. However, the shortest procedure was Electrophysiology procedure with 1 min as estimated in Switzerland while the longest procedure was Embolization in the head procedure with 135 min as estimated in USA [11].

Procedure	No. of images	Fluoro time(mins)	KAP Fluoro (Gy·cm ²)	Total KAP (Gy·cm ²)
Biliary Stent Positioning	6	3.73	5.11	13.43
Splenic Angiography	5	8.51	13.37	37.85
Abdominal Aorta Endoprosthesis	9.5	14.84	86.98	118.80
Biopsy	8.5	12.78	51.54	75.659
Intracranial Circulation	9	10.1	51.30	63.85
Percutaneous Liver Drainage	3.5	2.19	1.80	5.51
Catheter Embolization	9	11.17	64.67	92.12
Intraforaminal Infiltration	5	3.81	12.96	15.52
Percutaneous Nephrostomy	5	4.72	5.62	18.81

Table 11 Proposed DRL val

Table 12 International established DRL in	Procedure	Fluoroscopy time (mins)	KAP (Gy·cm ²)	
interventional procedure (12)		SWITZERLAND *12		
	Cerebral angiography	15	1,215	
	Coronary angiography	7	80	
	Electrophysiology	1	10	
	Hepatic embolization	30	620	
	Biliary drainage and stent insertion	25	240	
	Cerebral embolization	50	440	
	Iliac dilatation and stent insertion	25	460	
	Percutaneous coronary intervention	20	110	
		UNITED STATE *12		
	Biliary drainage	30	100	
	Pulmonary angiography	10	110	
	Renal or visceral angioplasty without stent	20	200	
	Renal or visceral angioplasty with stent	30	250	
	Iliac angioplasty without stent	20	250	
	Iliac angioplasty with stent	25	300	
	Bronchial artery embolization	50	240	
	Other tumor embolization	35	390	
	Embolization in the head for AVM	135	550	
	Embolization in the head for aneurysm	90	360	
	Pelvic artery embolization for trauma or tumor	35	550	
	Nephrostomy for obstruction	15	40	
	Embolization in the spine for AVM or tumor	130	950	
		SPAIN *12		
	Lower limb arteriography	10	73	
	Renal arteriography	9	89	
	Biliary drainage	20	80	
	Iliac stent	11	94	
	Uterine embolization	30	236	

9 Conclusion

Promotion of the use of the proposed DRLs in this study for interventional procedures are envisaged and essential for maintaining patient safety, optimizing radiation doses, ensuring consistency and quality in imaging and interventional practices, and promoting overall excellence in healthcare delivery. The proposed DRLs in this study is the first of its kind in Ghana involving five major hospitals. The nuclear regulatory authority is encouraged to promote the culture of the use of DRLs in angiography interventional procedures at the institutional level, while working towards establishment of a national DRL for the country.

9.1 Benefits

The results can be used as an effective tool that will aids • in optimisation of protection in the medical exposure of patients and staff for interventional procedures in Ghana.

- The results will provide information on the use of fluoroscopic guided techniques for interventional procedures in Ghana.
- The outcome of this study will serve and help suggests modifications in the conduct of interventional procedures in Ghana
- The outcome of this study highlights the importance of ٠ including significant radiation protection measures during fluoroscopic guided techniques and in training programmes for healthcare professionals working in interventional radiology.

9.2 Limitation

Fluoroscopic guided interventional procedures involved several complexities of the procedures with more patient specific assessment than the usual simple dose-related value in other procedure making it inappropriate to generalized.

- The observed distribution of patient doses is very wide, even for a specified protocol, because the duration and complexity of the fluoroscopic guided interventional procedures exposure is strongly dependent on the individual clinical circumstances
- This study could not account for the varied complexity of the various procedures, because the complexity index is difficult to assess because it requires several information on the anatomy and pathology of each single procedure.

9.3 Recommendation

- DRL was set at the 75th percentile of the distribution of the median doses from a survey conducted in five Centre in a country. A national data should be collected for more comprehensive national DRL across the country.
- The median value of the distribution can serve as an additional tool to aid in optimisation and may be a desirable goal at which to aim and represents a situation closer to the optimum use of the applied radiation.
- The complexity of the interventional procedures should be considered in setting the national DRL values, and a multiplying factor for the DRL value may be appropriate for more complex cases of a procedure.
- The median distribution of all the procedures performed in each of the five facilities should be used as Advisory Data Set for its clinical application.
- It is recommended that the benchmark data for each procedure should be compare to the median, 25th, and 75th percentile values of the facility data and used as a guide for it is application in clinical practice.
- Due to several factors including different patient sizes and difference in clinical pathologies, the use of the DRL should be flexible and not applied to individual patients' cases.
- The Equipment performance, equipment setup, operator's skills and experience, procedure protocol and complexity level of the group of procedures should be used as optimisation and investigation factors for DRL value above the threshold.
- Values lower than the DRLs may need optimization if the image quality is inadequate for the clinical task
- Due to the high values obtained in this study more radiation protection strategies should be aimed at optimizing the various procedures for more patient and staff safety during various interventional procedures.

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Availability of data and materials The data and materials for publication are all available upon request at any time.

Declarations

Ethics approval Approval was given for the research by the participating facilities and the ethical and Protocol Review Committee of the College of Basic and Applied Science, University of Ghana and the Participating Health Facilities. Additionally, the protocol and the application of same for this study was granted ethical clearance by the various Committees. The methods were performed in accordance with the guidelines and regulations as outline by the ethical and Protocol Review Committee of the College of Basic and Applied Science, University of Ghana and the Participating Health Facilities. All participants were assured of confidentiality and anonymity throughout the study.

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Conflict of interest The authors declare that they have no conflict of interest.

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