

RESEARCH ARTICLE

Quantitative Quality Assurance and Establishment of National Diagnostic Reference Levels for Adult General Radiography in Kenya

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Abstract

The leading diagnostic radiology equipment in developing countries is general radiography. Over 90% of the patients undergoing x-ray imaging are performed with radiographic equipment. Quality assurance (QA) therefore is critical towards ensuring quality imaging of the patients. A protocol form was developed and used to collect 1206 adult patient parameters and exposure factors that are in use during x-ray imaging at ten different facilities. Quality control (QC) tests were performed in the same facilities x-ray equipment and the radiation output used to calculate Entrance Surface Air Kerma (ESAK) for each examination. The ESAK results were used to derive the effective dose and each radiograph was assessed for clinical image quality by the radiologists at respective facility. The objective of which was to assess the x-ray equipment performance, ESAK, effective dose and image quality in adult radiographic examinations. The ESAK and effective dose for 24 types of general radiography examination projections were also determined. Most of the mean ESAK were above the Diagnostic Reference Levels (DRLs) published in the literature. The image quality assessments performed by the radiologists were 60% excellent, 33% good and 7% poor. To promote optimization of radiological protection of patients, the study proposed a national diagnostic reference levels (NDRL) for the 24 types of general radiography examinations projections.

Keywords: Quality Assurance; Diagnostic Reference Levels; Patient Dosimetry; Radiography

Introduction

The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) reported that magnitude and distribution of medical x-ray imaging is increasing across the world due to population increase and technological advances [1]. An earlier study in Kenya indicated that general radiography continues to be the most dominant procedure due to high disease prevalence [2]. Despite the critical role of x-ray imaging in diagnosis, there is little data on quality assurance programs that routinely monitor and assesses patient doses. New methodology for the determination of diagnostic reference levels, and establishing DRLs in radiography was well studied in numerous articles [3-6]. However, little is known about medical radiation exposures in Kenya, with a possibility of it being higher than the published diagnostic reference levels. The country, as typical of most developing countries, is faced with low technically skilled personnel as well as old, refurbished and some relatively newer radiological equipment [7]. The low technical level skills result in large film reject rates, poor image quality, waste of resources and unnecessary radiation exposure [8,9]. There is a need for imaging professionals and relevant stakeholders to co-operate and establish guidance levels or diagnostic reference levels (DRLs). The reference levels form a quality assurance tool that specifies the radiation levels above which appropriate action should be taken. A corrective action may also be considered when the radiation levels are substantially below the established guidance or reference level [10-12].

Quality assurance and assessment of typical patient dose forms the basis of operational application of quality improvement under As Low as Reasonably Achievable (ALARA) principle (IAEA). A few studies have been reported in Kenya on some radiographic

examinations, relative frequency, patient doses, and comparison with published international diagnostic reference levels, which shows considerable deviation in patient dose [2,7,8]. These studies indicated divergence in the application of justification and optimization. Yet none of the studies reported effective dose (E) levels or countrywide x-ray practice coverage. E is the primary quantity used to normalize partial-body irradiations relative to whole-body irradiation facilitating comparison of radiation exposure according to medical modalities, types of examinations and estimating potential detrimental effect. The optimization of radiological protection of patients in this study is considered to be dependent on clinical image quality and use of optimally performing x-ray equipment. This study aims to report the assessment of x-ray equipment performance, typical patient dose, and the image quality for representative hospitals across the country as compared to the recommendations of the international standards. This information could be used as a guide in the optimization and establishment of imaging guidelines tailored to the host country.

Methodology

General

The seven radiology departments in the study were randomly selected across the country from hospitals using speed screen film system [13]. The institutions that participated in the study identified a focal imaging technologist and radiologist within the radiology department. Image quality assessment forms were also provided to the facility radiologist. A questionnaire form was developed and provided to the participating facilities to record the equipment manufacturer, model, patient parameters, (patient age, gender, weight) and exposure factors (kVp, mAs) focus-film distance (FFD), focus-skin distance (FSD), focus size, filtration, use of grid, examination projection, and field size. At least ten randomly selected adults weighing 70±10 kg undergoing specified type of examination were required from each facility. The completed questionnaires were submitted through the post office, fax or email delivery systems. In the study, the data collected were categorized according to examination type and tabulated in the results section. The facilities that submitted the data were the visited by a medical physicist to perform x-ray equipment quality control tests and tube output for indirect calculation of ESAK.

X-ray Equipment Performance Tests

The x-ray equipment efficiency performance tests were performed on x-ray equipment at the respective medical facilities. The x-ray equipment tests parameters included kVp accuracy, kVp reproducibility, exposure time accuracy, exposure time reproducibility, light/radiation beam alignment, and total filtration (mm Al). The quality control tests were performed at a focus to detector distance (FDD) of one meter using a calibrated Unfors Xi Instrument (Unfors Instruments AB, Billdal, Sweden). The quality control test results were scored as one for 'Pass' or zero for a 'Fail' in accordance to the New South Wales Environment Protection Authority Methods and Standards [14]. The x-ray equipment efficiency performance tests were calculated as a percentage by dividing the total equipment quality control tests scored by the maximum score of nine points. The national QA level in general radiography was calculated as an average of the percentage score from each x-ray equipment performance tests results. A score above or equal to 75% was rated as excellent, 50-74.9% was rated as good, 30-49.9% was rated as fair, and less than 30% was rated as poor, in terms of performance assessment.

Patient Dose Assessment

At each facility that submitted the data, the x-ray tube output was measured using calibrated Unfors Xi Instrument. The incident air kerma K_i in mGy for the x-ray equipment for various exposure parameters (kVp and mAs) at one meter from the source were divided by the mAs used and the result plotted graphically against the kVp values. The measured x-ray tube output increased with a power of two in relation to kVp. The x-ray tube output factor in mGy per mAs was extracted from the graph and used for each patient exposure parameters to calculate K_{ip} using equation [1].

$$K_{ip} = M \times mAs \tag{1}$$

where M is the reading from the plotted x-ray tube output factor graph (mGy per mAs) at a specified voltage (kVp) and tube loading (*mAs*).

The ESAK for each patient was calculated indirectly using equation (2), by multiplying the incident air kerma with an appropriate backscatter factor (BSF). The different distances between the focus and the skin and the detector were corrected.

The DRLs used in this study were established from the calculated ESAK values, in accordance with the International Atomic Energy Agency guidelines [15]. The third quartile values for each type of examination was established and proposed as the initial NDRL. The relative uncertainties of the measured ESAK were evaluated using equation (3) assuming independent variables.

 $\sigma(p)$

where terms of the form P represent the relative uncertainties of the various variables p defined above. The entrance surface dose relationship to the effective dose was derived using conversion factors selected from published Monte Carlo simulation results for total patient radiation exposure for complete examinations [16]. Full details of the Monte Carlo techniques including the phantom description have been published by the National Radiological Protection Board [17]. Effective doses were calculated for each examination projection and summed to give the complete examination doses per patient.

Image Quality Assessment

The radiographs at each of the facility participating in the study were assessed by radiologists for image quality conformity according to European Commission (EC) quality criteria [11]. Radiologists were recommended to develop image quality guidelines similar to the European Commission standards for evaluating radiographs that were not included in the European Commission quality criteria. At least ten randomly selected adult patients per examination were required to be assessed by a radiologist at each facility. Image grading criteria of A, B or C was assigned to each radiograph independently by more than one radiologist. Grade A (excellent) meant anatomical features detected and fully reproduced, details visible and clearly defined, B (good) meant anatomical features just visible, details just visible but not clearly defined and C (poor) meant anatomical features invisible, details invisible and undefined.

Results

X-Ray Equipment Performance

The results of the quality control assessment of the x-ray equipment are presented in Table 1 below. The analysis of the measured quality control results indicated that the x-ray equipment efficiency performance of the seven machines in the study (I – VII) ranged from worst performing equipment 78% (VII) to best performing equipment 100% (II, III, V). The average x-ray equipment efficiency performance was 92%, a rank of "excellent" according to the study assessment criteria used.

	I	II	III	IV	v	VI	VII
X-ray equipment type	Toshiba Rotanode	Philips Medio 50 CP	Shimadzu Circlex	Philips Medio 50 CP	Philips Duodiagnost	Siemens Heliophos D	Meditronics Diagnox
Light/radiation beam alignment (< 1% FFD)							
Inside (cm)	-0.5	-1	0.2	0.8	-0.5	-0.5	- 3*
Outside (cm)	-0.2	-0.4	-0.5	0.5	0.1	-0.2	- 1 *
Anode Side (cm)	0.5	-0.8	-0.5	0.7	-0.2	0.5	- 0.1
Cathode Side (cm)	- 1 *	0.2	0.6	1 *	-0.4	- 1 *	+ 0.5
kVp Accuracy (5%)	± 1	± 1	± 1	± 1	± 1	± 1	4
kVp Reproducibility (2%)	± 1	± 1	± 1	± 1	± 1	± 1	0.5
Timer Accuracy (5%)	± 1	± 1	± 1	± 1	± 1	± 1	± 1
Timer Reproducibility (2%)	± 1	± 1	± 1	± 1	± 1	± 1	± 1
HVL (>2.3 mm Al)	2.8	2.79	2.84	2.82	2.79	3.11	3.2
Overall performance (%)	89	100	100	89	100	89	78

'Test failed; HVL measurements done at 70 kVp

Table 1: Quality control test performance results from seven representative x-ray equipment

Patient Dose Assessment

Table 2 and Table 3 contain the exposure parameters and radiation exposure involved in adults' general radiography examinations. The mean values of the tube potential and the beam filtration indicated a general preference of low kVp techniques suitable for small body sizes. In adult radiography, the DRLs currently available in the literature cover 30% of the procedures considered in the study. A total of 86% of the examinations were below the DRLs. The adult radiography examinations excluding extremities yielded effective doses (and potential detriment) that varied widely by a factor of about 1,000 (0.002–1.91mSv) between examination with a mean of 0.4 mSv. The variation was attributed to the type of imaging procedure performed, the exposure factors employed, equipment type and the amount of patient data that were not equal between the hospitals. The patient dose assessment method used in the study constituted of relative uncertainty of 13% derived from equation [3].

3

					EC Parameters			i
Exam.	kVp	mAs	Time (ms)	FFD (cm)	kVp	Time (ms)	FFD (cm)	Filtration (mm Al)
Chest PA	73(50-117)	7(1-32	50(6-322)	150(90-180)	125	< 20	140-200	≥ 3
Chest AP#	66(51-75)	8(2-50)	15(6-50)	100(70-112)	70-85	< 100	100-150	≥ 2.5
Chest LAT	83(63-115)	20(3-40)	80(15-160)	150(100-150)	70-85	< 100	100-150	≥ 3
Abdomen AP	78(60-96)	21(6-63)	120(30-250)	100(90-105)	75-90	< 200	100-150	≥ 1.3
Pelvis AP	75(68-96)	20(5-80)	130(25-320)	100(84-120)	75-90	< 400	100-150	≥ 3
L-spine AP	76(60-88)	25(6-80)	175(15-800)	90(84-120)	75-90	< 400	100-150	≥ 3
L-spine LAT	80(70-104)	36(10-110)	250(50-1000)	95(76-120)	80-100	< 1000	100-150	≥ 3
T-L spine AP	77(68-88)	40(10-80)	200(63-800)	98(90-107)	-	-	-	-
T-L spine LAT	80(73-90)	50(40-100)	225(83-400)	100(90-107)	-	-	-	-
T-spine AP	78(70-90)	50(3-160)	220(40-636)	100(90-107)	-	-	-	-
T-spine LAT	75(70-78)	70(32-160)	260(100-636)	100(90-107)	-	-	-	-
C-spine AP	70(63-77)	15(1-40)	80(50-100)	100(90-105)	-	-	-	-
C-spine LAT	70(63-85)	16(1-40)	90(62-100)	100(90-150)	-	-	-	-
Sinuses LAT	63(55-81)	8(3-22)	33(12-112)	100(90-105)	-	-	-	-
Skull AP	72(63-81)	20(4-50)	75(53-125)	100(90-105)	-	-	-	-
Skull LAT	68(60-75)	8(4-32)	80(55-130)	100(90-105)	-	-	-	-
Mandible PA	70(68-73)	22(14-40)	94(78-125)	100(90-105)	-	-	-	-
Hips AP	78(75-81)	7(5-10)	50(6-100)	100(90-105)	-	-	-	-
Hips LAT	73(70-75)	22(18-25)	115(70-100)	100(90-105)	-	-	-	-
Clavicle AP	67(63-77)	6(4-8)	20(15-32)	100(90-110)	-	-	-	-
Shoulder AP	71(66-77)	6(1-16)	35(26-50)	100(90-180)	-	-	-	-
Shoulder LAT	70(66-77)	7(1-16)	35(26-50)	90(90-100)	-	-	-	-
Upp. extr.	50(40-77)	3(0.2-8)	8(8-15)	100(87-150)	-	-	-	-
Low. extr.	54(42-77)	3(0.2-10)	12(6-20)	100(84-110)	-	-	-	-

EC: European Commission; FFD: focus to film distance; PA: posterior-Anterior; AP: anterior-posterior; LAT: lateral; #None grid; Dash (—) indicates radiographic parameters not available. **Table 2:** Mean (range) adult exposure factors and EC recommended radiographic parameters [11]

Exam	N	Age (yrs)	Body thickness (cm)	Height (cm)	Weight (Kg)	ESAK (mGy)	NDRLs (mGy)	DRL (mGy)	E in mSv	E 3Q	E values in literature
Chest PA	418	39(16- 82)	21(13-38)	168(71- 240)	69(39- 180)	0.5(0.1- 4)	0.5	0.3 ^{a,b, d} , 0.15,0.25 ^d , 0.4b	0.05(0.01- 0.42)	0.05	0.02(0.05-0.24) °, 0.014°
Chest AP	20	42(17- 86)	20(12-37)	165(68- 240)	70(41- 186)	0.8(0.2- 2)	1	-	0.08(0.02- 0.19)	0.1	-
Chest LAT	14	27(16- 56)	24(16-31)	165(157- 174)	64(48- 78)	2(0.2-6)	5	$1.5^{a,b,d}$, 0.6^{d} ,	0.24(0.02- 0.62)	0.5	0.1(0.05-0.24)°, 0.038°
Abdomen AP	29	32(16- 68)	20(15-28)	165(140- 178)	76(59- 92)	4(0.6-23)	4	6ª, 4,10,4.5 ^d	0.6(0.1-3)	0.6	0.7(0.04-1.1) ^c , 0.429 ^e
Pelvis AP	33	47(26- 82)	22(12-36)	168(160- 184)	70(35- 102)	4(0.4-14)	5	7ª,10 ^{a,b,d} , 4 ^d	0.6(0.06-2)	0.9	0.6(0.2-1.2) ^c , 0.284 ^e
L-spine AP	27	44(15- 84)	24(10-40)	164(150- 179)	73(40- 162)	4(1-17)	5	8^{a} , $10^{b,d}$, 5^{d}	0.5(0.1-1.8)	0.5	1.5(0.5-1.8) ^c , 0.389 ^e
L-spine LAT	51	44(15- 84)	25(14-33)	163(150- 179)	74(40- 162)	8(1-34)	11	24ª,30 ^{b,d} , 11 ^d	0.9(0.1-3.6)	1.2	1.5(0.5-1.8)°, 0.211°
T-L spine AP	15	51(23- 84)	24(15-40)	163(157- 167)	72(52- 105)	6(1-20)	10	-	1.7(0.7-3.1)	2.3	0.238 ^e
T-L spine LAT	12	43(16- 86)	26(18-32)	162(148- 182)	71(53- 116)	15(5-30)	24	-	1.9(0.6-3)	2.6	0.144 ^e
T-spine AP	16	41(16- 91)	23(21-26)	158(72- 187)	68(52- 90)	4(0.15- 13)	7	5.1ª, 4,7 ^d	0.4(0.01- 1.25)	0.7	1(0.6-1.4)°, 0.238°

T-spine I AT	12	30(21-	19(10-26)	162(150-	71(43-	12(5-34)	9	16 2ª 7 12d	1(0.5-3)	0.8	1(0.6-1.4)°,
1-spine LAI	12	37)	19(10-20)	179)	162)	12(5-54)	,	10.2 , 7,12	1(0.3-3)	0.8	0.144 ^e
C-spine AP	13	43(33- 50)	15(10-20)	160(152- 169)	63(52- 96)	1(0.3-6)	2	-	0.06(0.01- 0.2)	0.08	0.2(0.07-0.3) ^c , 0.018 ^e
C-spine LAT	11	42(33- 50)	15(10-18)	160(148- 172)	68(56- 98)	2(0.1-5)	3	-	0.06(0.01- 0.2)	0.1	0.2(0.07-0.3) ^c , 0.018 ^e
Sinuses LAT	13	34(19- 49)	8(5-10)	153(70- 177)	69(52- 84)	0.7(0.2- 1)	1	-	0.01(0.002- 0.02)	0.02	0.016 ^e
Skull AP	28	40(25- 68)	14(8-36)	150(70- 177)	65(52- 84)	4(0.2-15)	7	5 ^{a,b} , 2 ^d ,	0.03(0.0012- 0.2)	0.07	0.1(0.03-0.22) ^c , 0.033 ^e
Skull LAT	13	38(17- 68)	7(5-15)	150(70- 177)	68(52- 90)	0.6(0.2- 5)	0.3	3 ^{a,b} , 1.3 ^d	0.006(0.001- 0.05)	0.003	0.1(0.03-0.22) ^c , 0.016 ^e
Mandible AP	13	22(18- 26)	22(16-30)	163(160- 166)	55(50- 60)	2(0.7-7)	3	-	0.02(0.007- 0.07)	0.03	0.016 ^e
Hips AP	12	32(18- 50)	22(15-25)	164(153- 172)	55(33- 67)	0.5(0.3- 1.2)	0.7	-	0.03(0.02- 0.07)	0.04	0.7(0.18-2.71) ^c , 0.191 ^e
Hips LAT	12	35(17- 50)	24(19-26)	162(151- 169)	55(33- 67)	1.5(0.7- 2)	1.8	-	0.08(0.04- 0.14)	0.1	0.7(0.18-2.71) ^c , 0.191 ^e
Clavicle AP	13	33(17- 72)	10(6-14)	167(152- 183)	73(46- 125)	0.2(0.2- 0.4)	0.3	-	0.002(0.001- 0.003)	0.002	0.007 ^e
Shoulder AP	15	47(27- 80)	14(8-18)	165(152- 179)	70(41- 120)	0.7(0.1- 4)	0.5	-	0.01(0.001- 0.02)	0.003	0.01°, 0.007°
Shoulder LAT	10	24(16- 41)	15(9-17)	159(148- 182)	72(52- 116)	1(0.1-4)	2		0.01(0.001- 0.03)	0.02	0.01°, 0.004°
Upp. extr.	155	35(16- 90)	4(1-18)	155(63- 193)	66(45- 100)	0.1(0.01- 1.5)	0.1	-	0.003(6E-5- 0.05)	4.00E- 04	0.001(0.0002- 0.1) ^c , 0.0001 ^e
Low. extr.	251	37(16- 80)	5(1-23)	166(101- 193)	69(33- 108)	0.1(0.01- 1)	0.1		0.001(6E-5- 0.004)	1.00E- 03	0.001(0.0002- 0.1) ^c , 0.0001 ^e

a = [3]; b = [4]; c = [5]; d = [6]; e = [18]; Dash (--) indicates radiographic parameters not available**Table 3:**Mean (range) patient parameters and dose for adult radiography examination

Clinical Image Quality Assessment

Figure 1 indicates the relative distribution of the radiologists' image quality assessment results. The country's image quality performance averaged over the participating hospitals was as follows: 60% graded A, 33% graded B, and 7% graded C respectively. A good approximation method for the overall film reject for a department was determined in a previous study that it could be obtained by multiplying by two the percentage value obtained for grade C at the radiologist level [2]. The newly calculated estimate of 14% will therefore include the film rejects at the imaging technologist assessment level.



Figure 1: Radiologists' level image quality assessment per hospital

Discussion

X-Ray Equipment Performance

The accuracy of exposure factors was essential to achieving repetitive high quality diagnostic clinical images. The observed kVp accuracy, consistency test and timer accuracy indicated good generator performance in majority of the facilities involved in the

study. The overall x-ray equipment QC results obtained in this study were indicative of proper functioning of the tube voltage, tube current, and the x-ray tube total filtration [19]. The beam quality results were also consistent with the American Association of Physicists in Medicine recommendation for all the tube settings on any focal spot size and kVp [20]. The average performance in collimator test for all the x-ray equipment assessed showed a frequent shift of mirror position, or collimator position, in the tube head. The collimation test performance indicators showed proper handling of xray equipment also associated with the equipment age and workload. The collimation test should therefore form part of the imaging technologist routine QC test. Improper collimation results in unnecessary patient dose and scatter radiation affects image contrast. The facilities participating in the study were provided with an assessment report following this study. Imaging professionals were also advised not to rely wholly on the QC tests performed by service and maintenance engineers, but to adopt standardized QC tests, QA training as well as need to establish a QA program.

Examination Frequency, Imaging Techniques and Patient Doses

The radiographic examinations of the chest, extremities, and pelvis occurred with the highest frequency. This high examination frequency was attributed to lung infections, HIV/AIDS prevalence, motor vehicle accidents, and cases of assault, chronic constipation, and intestinal obstruction, which could also be linked to parasitic infestations. In general, the increased radiological examinations showed a growing appreciation of the important role played by x-ray imaging in patient pathology diagnosis and management [8].

The chest examination showed the least compliance with the EC recommended radiographic technique and DRLs [11]. Examinations of the spine, the abdomen, and the pelvis were compliant with the EC recommended radiographic technique and DRLs but constituted the largest proportion of patient radiation dose. This result therefore revealed a new perspective of optimization that could be exploited. To attain optimization in adult radiography, the following is recommended for nationwide adoption: high kVp radiographic techniques, standard focus to film distances, maintenance of optimal device performance, use of local DRLs, regular image quality assessment, and suitable choice of x-ray equipment during procurement. The manufactures are also recommended to fit all x-ray equipment with dosimeters for effective routine patient dose measurement and recording.

The average estimated body depths did not significantly affect patient dose in adults. However, the body weight showed an effect in the measured patient dose especially on the spine and pelvis examinations. There is a need for specific radiology facilities to collect and analyze exposure and patient parameters so as to develop an institutional quality management system that is commensurate with complexity of a specific radiological procedure and the body habitus of the patient. This approach would facilitate a comparison between diagnostic facilities nationally and internationally, including the adoption of European Commission radiographic technical factors [11]. In developing countries typical of Kenya, this could be hampered by the training cost and absence of integrated kerma area product (KAP) meters in the x-ray equipment that are already in use. Having built-in dosimeters in the x-ray equipment would facilitate the setting of dose action levels, local DRLs, and validation of optimal imaging techniques. The effective doses were estimated in order for the imaging professionals to get a better understanding between exposure situations and facilitate dose reduction through optimization.

Image Quality of Radiographs

The magnitude of patient dose due to rejects, poor use of equipment, poor radiographic techniques, and equipment age can be significant if quality assurance continue to be inadequate. High film rejects result in an unnecessary cost, which can be avoided if effective and efficient quality assurance programs are established. The quality improvement processes within radiological facilities could be enhanced through accreditation of diagnostic facilities, compliance assurance audits and inspections, as well as surveillance programs being conducted by recognized professional associations or regulating bodies. Adequate equipment selection (including built-in dosimeters) combined with an adequate quality assurance program assure operational patient radiation protection. The use of high speed film screens contributes to compliance with DRLs without compromising the diagnostic value of the images.

The relationship between radiation exposure parameters and image quality is essential to radiologists to institute corrective optimization measures without significant loss of clinical information. The outcome of poor image quality graded C represents unnecessary radiation exposure to patients resulting in repeated radiographs, and wastage of resources. The quality assessment methodology developed from this study could therefore be adopted by imaging professionals to help establish accreditation and benchmarking of diagnostic radiology departments in various facilities.

Conclusion

The overall country performance level was placed at 88% and 86% in the general x-ray equipment and patient dose performance level respectively. National diagnostic reference levels for 24 types of general radiography examinations metrics were proposed. The national image quality performance was rated at 60% with a 14% film reject rate. There is room for the expansion of the present study and improvement in areas such as optimal image quality performance through regular training and upskills of imaging technologist.

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