PHYSICS

Variabilities in X-ray diagnostic reference levels

Thibault Vanaudenhove[1] · Alain Van Muylem[2] · Nigel Howarth[3] · Pierre Alain Gevenois[4] · Denis Tack[5]

Abstract

Objectives To estimate the variability of X-ray diagnostic reference levels (DRLs) depending on the number of X-ray devices and data per device.

Methods Dose-area products (DAP) were collected by the national nuclear control agency from the 590 devices installed in 345 medical centers in the country. From 2015 to 2017, the number of chest (postero-anterior (PA) view alone, and both postero-anterior and lateral views (PA/LAT)), abdomen, pelvis, and lumbar spine examinations collected in these centers ranged from 23,000 to 77,000. The impact of the number of devices and DAP data per device on DRLs' variabilities (95th confidence intervals divided by medians) is estimated using a bootstrapping method as a function of the number of devices and DAP per device.

Results The DRLs' variabilities ranged from 30 to 200% depending on the number of devices and DAP data per device but stabilized at 30% when the number of devices was higher than 200 for chest PA and abdomen examinations, 300 for lumbar spine and pelvis examinations, and 400 for chest PA/LAT examinations, regardless of the number of DAP data per device. Extrapolations of our results suggest that thousands of devices are necessary to reduce DRLs' variabilities to 10%.

Conclusion DAP-related DRL variabilities are high but only moderately influenced by the number of DAP data per device and of devices provided this number is higher than 200 to 400 devices according to the type of examination. Harmonization of methods of data collection between the authorities of the EU states should be recommended.

Key Points

• *DAP-related DRLs are not fixed values but ranges of values with at least 30% variability.*

• *DAP-related DRLs strongly depend on the number of devices included when lower than 100.*

• *If the number of devices included exceeds 200 to 400, the DRLs' variabilities do not depend on the number of DAP per device and should not exceed 30%.*

Keywords Radiation protection · Radiography · Surveys and questionnaires

Abbreviations

CT	Computed tomography
DAP	Dose-area product
DLP	Dose-length product
DRL	Diagnostic reference level
EU	European Union
P75	75th percentiles
PA/LAT	Postero-anterior and lateral views

✉ Denis Tack
denis.tack@skynet.be

1 Federal Agency for Nuclear Control (FANC), Rue Ravenstein 36, 1000 Brussels, Belgium

2 Department of Chest Medicine, Hôpital Erasme, Route de Lennik 808, 1070 Brussels, Belgium

3 Department of Radiology, Clinique des Grangettes, 7 Chemin des Grangettes, 1224 Chêne-Bougeries, Switzerland

4 Department of Radiology, Hôpital Erasme, Route de Lennik 808, 1070 Brussels, Belgium

5 Department of Radiology, Epicura, Clinique Louis Caty, 136 Rue Louis Caty, 7331 Baudour, Belgium

Introduction

Establishing diagnostic reference levels (DRLs) of radiation dose delivered by X-ray examinations is mandatory in European Union (EU) member states [1, 2]. The 75th percentiles (P75) of dose distributions define DRLs and are considered the upper limit of good medical practice [3–9]. The EU recommends a method based on that used in the UK for establishing these distributions but its application in each EU member state is at the discretion of the national authorities [1, 2, 8, 9]. This

method was originally based on collecting dose values in ten consecutive so-called standard weight patients (i.e., 70 ± 3 kg) for any given examination and has been adapted in EU states in different manners. First, as recruiting "standard weight patients" can be difficult, some national authorities disregard weight and size criteria but request sample sizes larger than ten and up to 50 consecutive patients [6, 10–16]. Second, whereas the original method recommended collecting data from all devices installed in the country, some national authorities accept a voluntary contribution from each center, limiting the collection to 20 to 30% of installed devices [6–12]. It has recently been shown that at a local level, variability of DAP values depends on the number of DAP data collected and could be quite high for samples as small as 50 per device [17]. In addition, recent research at national level on CT related DRLs' variabilities showed that DRLs should be regarded as a range of values rather than a fixed absolute value [17, 18]. These observations raise the hypothesis that the variability of DAP-related DRLs could also be regarded as a range of values rather than a fixed value. The purpose of this study was therefore to test this hypothesis by assessing the variability of DAP-related DRLs depending on the number of DAP data per device and the number of devices included in surveys.

Materials and methods

According to EU legislation (i.e., the Regulation (EU) 2016/679 regarding the protection of data of individuals), a purely observational study with complete anonymization of the data at the source, which removes any possibility of identifying the individual patients, is not subject to ethical review [19]. We analyzed radiographic dose indicators of chest (single postero-anterior (PA) view and combined postero-anterior and lateral (PA/LAT) view examinations, and both postero-anterior and lateral views (PA/LAT) examinations), abdomen, pelvis, and lumbar spine examinations, anonymized at the source, and collected by the national agency in charge of nuclear control in our country (Belgium) from 2015 to 2017. For each examination, the collected dose indicator was the DAP along with patient's gender and age.

At the time of the study, 590 radiographic X-ray devices were installed in our country in 345 medical centers. These centers are obliged by law to undergo yearly quality control, to complete surveys on X-ray dose every 3 years and to provide anonymized dose indicator values for given standard examinations delivered to a minimum of 50 consecutive patients or, if less than 50, for all examinations performed within a 3-month period. For each examination, we considered the sum of DAPs of all views. The number of X-ray devices and patients' data collected during the study period are displayed in Table 1 for the five examinations selected.

Statistical analyses

For a given examination, a database of M devices named M_i (with i ranging from 1 to M) was established. Each device provided a corresponding N_i number of DAP values. As recently recommended by the IRCP and confirmed in a previous work on CT-DRLs, we only considered median values per device, and not mean values [3, 18].

First analysis

Step 1

For a given device M_i, a random DAP sample of size n_j was drawn with replacement from its DAP distribution. From this sample, a median μ_{ij} was computed. By repeating this procedure 2000 times (yielding $\mu_{ij}(1)$, $\mu_{ij}(2)$, ..., $\mu_{ij}(2000)$), the sampling distribution of μ_{ij} was derived and stored. This procedure is illustrated in panel a of Fig. 1. The procedure was repeated for

Table 1 Number of X-ray devices and DAP data per device

Body region		Chest PA	Chest PA/LAT	Abdomen	Lumbar spine	Pelvis
Number of DAP data at national level		36,332	76,687	22,627	25,756	24,616
Number of devices at national level		352	473	424	451	442
Number of devices with number of DAP data	> 5	312	464	366	405	401
	≥ 20	271	431	264	322	322
	≥ 50	179	316	163	191	141
	≥ 100	55	110	59	54	44
	≥ 200	34	57	20	23	24
	≥ 500	12	26	4	4	3
	≥ 1000	7	15	0	1	1

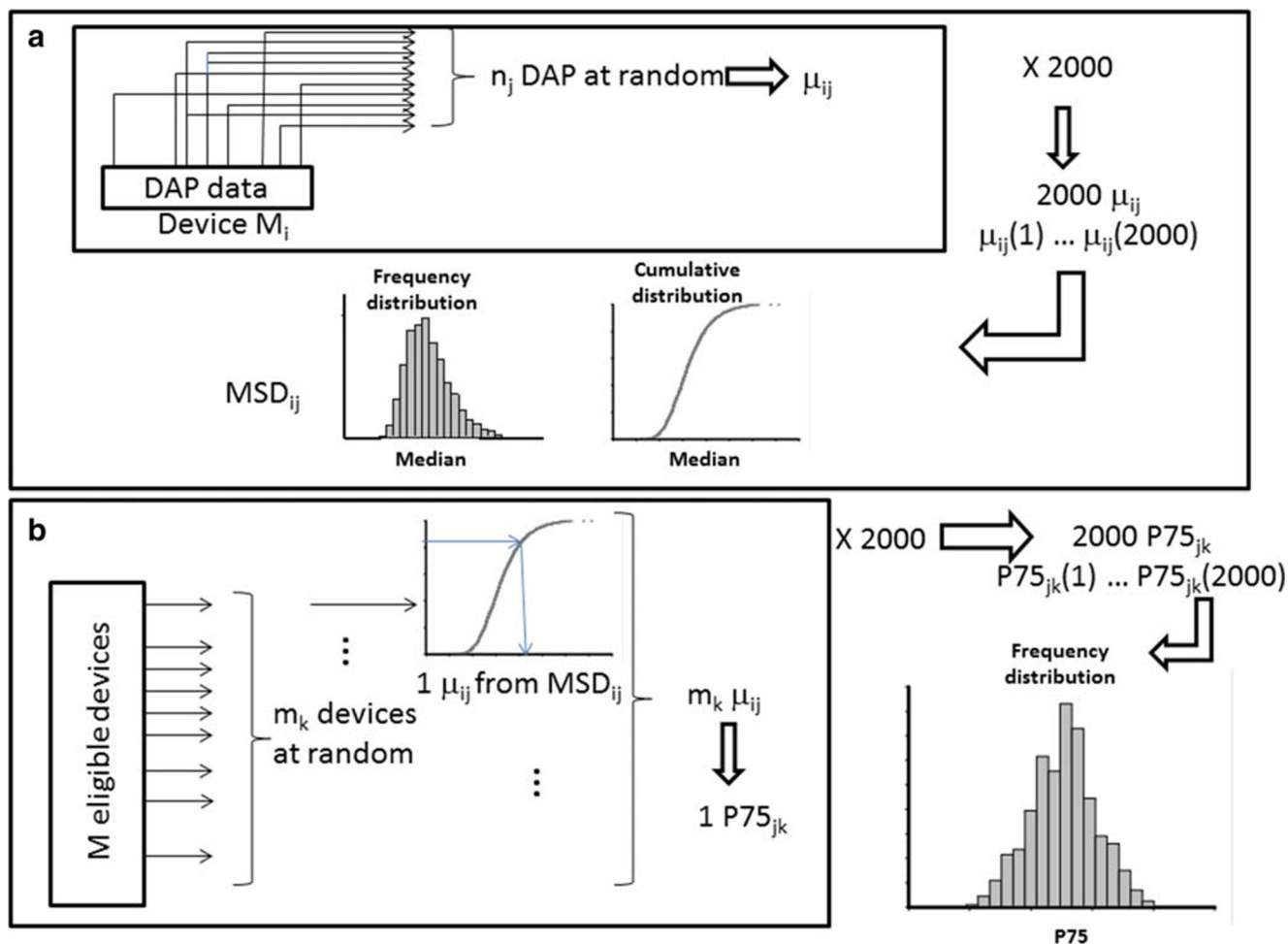All devices at national level participated to the survey as this is a legal requirement

Fig. 1 Graph illustrating statistical method. **a** The first step of the statistical analysis and (**b**) the second one

each device and for four sample sizes ($j = 1...4$, $n_1 = 10$, $n_2 = 20$, $n_3 = 50$, $n_4 = 100$). At this stage, M × 4 median sampling distributions MSD_{ij} were established for the M devices ($i = 1...M$) and the four considered sample sizes ($j = 1...5$).

Step 2

Out of the M devices, m_k devices were drawn at random with replacement. For each of the m_k-drawn devices and a given sample size n_j, one μ_{ij} value was drawn at random from MSD_{ij} (i being the index of the device considered). The 75th percentile of this sample of m_k values was computed giving $P75_{jk}$ (for a sample size n_j and a number of devices m_k). This procedure is illustrated in panel b of Fig. 1. We considered five numbers of devices ($k = 1...5$, $m_1 = 10$, $m_2 = 20$, $m_3 = 30$, $m_4 = 50$, $m_5 = 100$). By repeating this procedure 2000 times (yielding $P75_{jk}(1)$, $P75_{jk}(2)$, ..., $P75_{jk}(2000)$), the sampling distribution of $P75_{jk}$ was derived. From this distribution, the median and the 95% confidence interval (percentile 97.5–percentile 2.5) of P75 were computed. DRLs' variabilities were defined as the 95% confidence interval of DRLs divided by their medians [18].

Second analysis

A second analysis similar to the first one was performed including all devices with at least 20 DAP data. For each of these devices, i.e., with at least 20 DAP data per examination type, all DAPs were included in the analysis and the P75 variability computed as a function of the number of devices from 10 up to the number available according to the different X-ray examinations (Table 1). For each examination, the number of devices needed to reach variabilities of 25% and 10% was computed by adjusting a power model $CI95\% = a.b^{\text{number of devices}}$, providing extrapolated CI95% values.

Results

The relationships between both the number of X-ray devices included in a survey and that of DAP data per device and DRLs' variability are shown in Fig. 2 for chest (PA alone, and PA/LAT), abdomen, pelvis, and lumbar spine
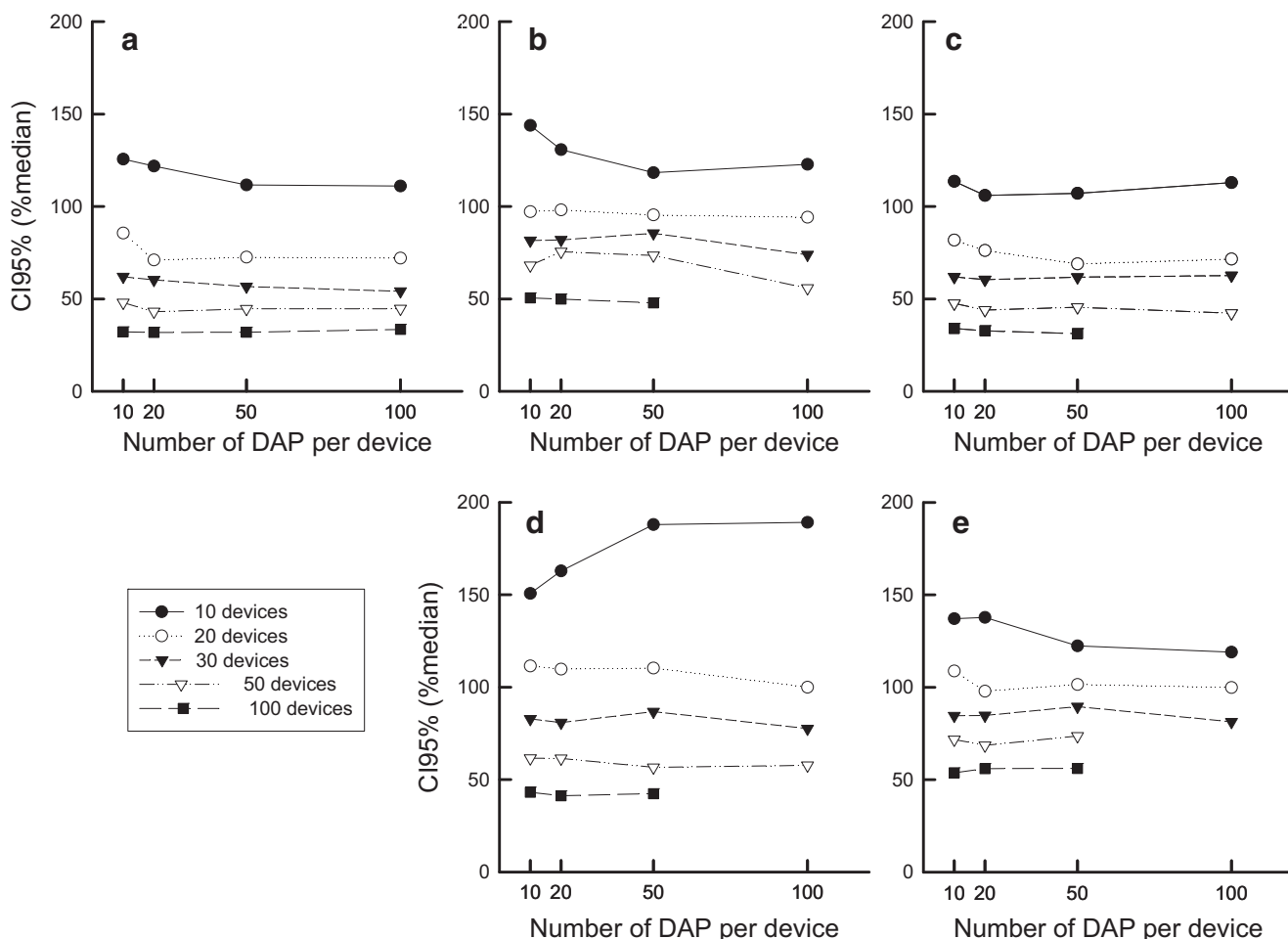
Fig. 2 a–e DRL (P75) variability (CI95%/median) as a function of the number *n* of devices considered (*n* = 10, 20, 30, 50, and 100: linked symbols) and the number m of DAP values per device (x-axis: *m* = 10, 20, 50, and 100). **a** Chest PA, (**b**) chest PA/LAT, (**c**) abdomen, (**d**) lumbar spine, (**e**) pelvis. Missing dots are due to insufficient number of devices with the required number of DAP

examinations. This figure illustrates that DRLs' variability was almost never influenced by the number of DAP data per device provided at least 20 DAP data per device and 20–30 devices were included.

DRL values and their variabilities—computed from devices with at least 20 available DAP data—are listed in Table 2, and variabilities as a function of the number of devices are illustrated in Fig. 3. This figure illustrates that DRLs' variabilities were

Table 2 P75 variability observed by including all devices with a number of DAP ≥ 20

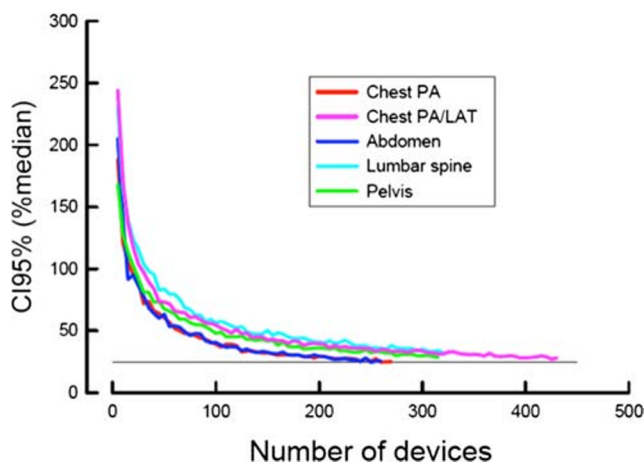|	Number of devices	Variability
Chest PA	271	25.0
Chest PA/LAT	431	27.9
Abdomen	264	25.6
Lumbar spine	322	32.3
Pelvis	320	28.3

Fig. 3 Variability (CI95 in percentage of median) of P75 sampling distribution as a function of the number of devices considered. Each device provided a DAP median computed by using all DAP values available for this device. Inclusion criterion for a device is number of DAP values ≥ 20. The horizontal line corresponds to a variability equal to 25%

strongly dependent on the number of devices and almost stable around 25 to 30% provided that the number of devices exceeded 250 (for PA/LAT chest and abdomen examinations) and up to 400 (for PA chest, lumbar spine, and pelvis examinations). By fitting a power model on the CI95% curves shown in Fig. 3 (R-squared between 0.991 and 0.996), the number of devices needed to reach CI95% equal to 25% and 10% were extrapolated (Table 3). Twenty-five percent variability could only be reached with at least 480, 470, and 590 devices respectively for PA/LAT chest, pelvis, and lumbar spine examinations. The number of devices needed to reach 10% variability grew up from 1500 for PA/LAT chest and abdomen examinations to 4000 for lumbar spine examinations. Such numbers are unattainable in our country.

Discussion

This study shows (1) that DAP-related DRL variabilities range from 30 to 200% and are higher than DLP-related DRL variabilities [20]; (2) that DAP-related DRL variabilities are moderately dependent on both the number of DAP data per device and the number of devices if higher than 250 to 400 devices, depending on the body region imaged; and (3) that much higher numbers of devices (thousands) are needed to lower the variability down to 10%. These results deserve further discussion at the level of international authorities, national authorities, and radiology departments.

For international authorities, caution is essential when comparing DRLs between countries (with subsequent rankings) because (1) patients' body habitus, a major determinant of the delivered radiation doses, may differ between countries [20], and (2) the number of devices included in surveys—which may also substantially differ between countries and be very low in small countries—has a significant impact on the DRLs variability, as revealed by this study.

Table 3 Number of devices needed to achieve a given P75 variability

	Number of devices*		
	Variability = 25%	Variability = 10%	R^2
Chest PA	260	1550	0.993
Chest PA/LAT	480	3170	0.996
Abdomen	260	1510	0.991
Lumbar spine	590	4090	0.994
Pelvis	470	3760	0.993

*Values were extrapolated from the data depicted on Fig. 2 by fitting a power model CI95% = a.(number of devices)^b. The R-squared (R^2) of the fitting is presented in the last column

For national authorities, sufficient numbers of devices should be surveyed to provide confident DRLs. The original recommendation is to conduct an initial survey with 20–30 devices and then to increase this number in subsequent surveys [8, 9, 14, 15]. Our study suggests that much higher numbers of devices should be included. Indeed, by including more than 200 devices, DRL variabilities would be reduced from 150% to less than 50%. With 400 devices, DRL variabilities would be reduced to 25%. Such high numbers of devices—reasonably achievable in large countries—could be attained in our country only if all the devices installed were included. More importantly, when more than 200 devices are included, their number influences DRLs' variabilities only weakly, regardless of the number of DAP data per device.

For radiology departments, our data confirm that variabilities of DAP-related DRLs are quite high. These variabilities should be added to those of DAPmeters themselves which have a tolerance of up to ± 30%. Both DRL and local DAP data variabilities should be taken into consideration in process of dose optimization, as they could lead to inappropriate dose reduction, with subsequent impaired image quality or, on the contrary, to inappropriately recommending a need for optimization, with subsequent excessively high radiation doses [16]. Only radiology departments with extremely high DAP medians would be capable of taking appropriate decisions over the need for optimization. The uncertainties on both DAP and DAP-related DRLs are indeed very high and even much higher than those reported in CT dose surveys [21]. The results of this study and those previously reported on DAP variabilities per device [17] raise the question of whether current survey methods can actually identify outliers and assist in dose optimization processes or not.

Recommendations aiming at improving dose surveys can be suggested. First, to establish reliable DRLs with an error minimized to 25% of their current values, at least 250 to 400 devices and 20 data per device have to be included. This scenario however is not feasible in countries with low numbers of devices installed. Second, local data collection should be exhaustive, ideally through dose tracking software, in order to minimize uncertainties when comparing with DRLs. Third, as both DRL and local DAP data variabilities reinforce each other, national authorities should reflect carefully on whether any penalty should be inflicted on a department with devices delivering doses higher than DRLs.

This study has some limitations. First, it was limited to examinations of four regions as our national agency only collects DAP data from the most frequently performed examinations and focused on the most radiosensitive organs. Second, the small size of our country prevented us from considering real data and forced us to extrapolate the numbers of devices necessary to achieve DLR variabilities lower than 25%, down to 10%. Third, it would be important to distinguish the type of X-ray devices involved in surveys, whether direct radiology

(DR) devices or computed radiography (CR) devices. Indeed, radiation dose is dependent on the technique used, but we were unable to investigate them separately because of the paucity of data available from CR devices.

In conclusion, DAP-related DRL variabilities are high but moderately influenced by the number of DAP data per device and the number of devices, provided this number exceeds a few hundreds. These variabilities can lead to significant uncertainty concerning the need for dose optimization. As differences in methods of evaluating survey data can artificially influence DRLs, harmonization of these methods should be recommended between the authorities of the EU states.

Compliance with ethical standards

Guarantor The scientific guarantor of this publication is Denis Tack.

Conflict of interest The authors of this manuscript declare no relationships with any companies whose products or services may be related to the subject matter of the article.

Statistics and biometry One of the authors has significant statistical expertise.

Informed consent Written informed consent was not required for this study since, according to EU legislation (i.e., the Regulation (EU) 2016/679 regarding the protection of data of individuals), a purely observational study with complete anonymization of the data at the source, which removes any possibility of identifying the individual patients, is not subject to ethical review. See "The European parliament and the council of the European Union (2016) Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC. OJ L 119, 4.5.2016, p. 1–88. Available via https://op.europa.eu/en/publication-detail/-/publication/3e485e15-11bd-11e6-ba9a-01aa75ed71a1/ Accessed 24 Oct 2019."

Ethical approval Institutional Review Board approval was not required because see above.

Methodology
• Retrospective
• Observational
• Multicenter study

References

1. The council of the European Union (1997) Council Directive 97/43 of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom. Available via https://eur-lex.europa.eu/eli/dir/1997/43/oj. Accessed 20 Oct 2019
2. The council of the European Union (2013) Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom. Available via https://eur-lex.europa.eu/eli/dir/2013/59/oj. Accessed 20 Oct 2019
3. Vaño E, Miller DL, Martin CJ et al (2017) ICRP publication 135: diagnostic reference levels in medical imaging. Ann. ICRP 46:1–144
4. Office Fédéral de Santé Publique (2010) Niveaux de référence diagnostiques. Available via https://www.bag.admin.ch/bag/fr/home/gesetze-und-bewilligungen/gesuche-bewilligungen/bewilligungen-aufsicht-im-strahlenschutz/informationen-fuer-medizinische-betriebe/diagnostische-referenzwerte-im-strahlenschutz.html. Accessed 20 Oct 2019
5. Agence fédérale de Contrôle nucléaire (2015) Niveaux de référence diagnostiques en radiologie. Available via https://afcn.fgov.be/fr/professionnels/professions-medicales/applications-radiologiques/nrd. Accessed 20 Oct 2016
6. Stamm G (2012) Collective radiation dose from MDCT. Critical review of survey studies. In: Tack D, Kalra MK, Gevenois PA (eds) Radiation dose from multidetector CT. Springer, Heidelberg, pp 209–229
7. Tack D, Jahnen A, Kohler S et al (2014) Multidetector CT radiation dose optimisation in adults: short- and long-term effects of a clinical audit. Eur Radiol 24:169–175
8. European commission (1998) Radiation Protection 102: implementation of the medical exposure Directive (97/43/Euratom). Proceedings of the international workshop held in Madrid on 27 April 1997. Available via http://ec.europa.eu/energy/sites/ener/files/documents/102_en_0.pdf. Accessed 21 Oct 2019
9. European commission (1999) Radiation Protection 109: guidance on diagnostic reference levels for medical exposures. Available via https://ec.europa.eu/energy/sites/ener/files/documents/109_en.pdf. Accessed 21 Oct 2019
10. Shrimpton PC, Hillier MC, Lewis MA, Dunn M (2006) National survey of doses from CT in the UK: 2003. Br J Radiol 79:968–980
11. Jessen KA, Shrimpton PC, Geleijns J, Panzer W, Tosi G (1999) Dosimetry for optimisation of patient protection in computed tomography. Appl Radiat Isot 50:165–172
12. Institut de Radioprotection et de Sûreté Nucléaire (2010) Doses délivrées aux patients en scanographie et en radiologie conventionnelle. Résultats d'une enquête multicentrique en secteur public. Rapport DRPH/SER N°2010–12. Available via http://www.irsn.fr/FR/expertise/rapports_expertise/Documents/radioprotection/IRSN-Rapport-dosimetrie-patient-2010-12.pdf. Accessed 22 Sep 2019
13. Agence fédérale de Contrôle nucléaire (2011) La dosimétrie des patients - Arrêté de l'Agence fédérale de contrôle nucléaire du 28 septembre 2011 concernant la dosimétrie des patients. Available via http://www.jurion.fanc.fgov.be/jurdb-consult/consultatieLink?wettekstId=15119&appLang=fr&wettekstLang=fr. Accessed 20 Oct 2019
14. National Radiological Protection Board (1992) National Protocol for patient dose measurements in diagnostic radiology. Chilton. Available via https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/337175/National_Protocol_for_Patient_Dose_Measurements_in_Diagnostic_Radiology_for_website.pdf. Accessed 20 Oct 2019
15. European Commission (2008) European guidance on estimating population doses from medical X-ray procedures. Radiation Protection 154. Luxembourg. Available via https://ec.europa.eu/energy/sites/ener/files/documents/154.zip. Accessed 21 Oct 2019
16. European Commission (2014) Diagnostic Reference Levels in thirty six European countries. Part 2/2. Radiation Protection 180. Luxembourg. Available via https://ec.europa.eu/energy/sites/ener/files/documents/RP180%20part2.pdf. Accessed 21 Oct 2019

17. Taylor S, Van Muylem A, Howarth N, Gevenois PA, Tack D (2019) X-ray examination dose surveys: how accurate are my results? Eur Radiol 2019;10:5307–5313

18. Taylor S, Van Muylem A, Howarth N, Gevenois PA, Tack D (2017) CT dose survey in adults: what sample size for what precision? Eur Radiol 27(1):365–373

19. The European parliament and the council of the European Union (2016) Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC. OJ L 119, 4.5.2016, p. 1–88. Available via https://op.europa.eu/en/publication-detail/-/publication/3e485e15-11bd-11e6-ba9a-01aa75ed71a1/ Accessed 24 Oct 2019

20. de Saint Pol T (2006) Corps et appartenance sociale : la corpulence en Europe. Données sociales 2006 - La société française, Institut National de la Statistique et des Etudes Economiques, pp.649–656. Available via https://halshs.archives-ouvertes.fr/halshs-00109017/document

21. Vanaudenhove T, Van Muylem A, Howarth N, Gevenois PA, Tack D (2019) CT diagnostic reference levels: are they appropriately computed? Eur Radiol 10:5264–5271