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Original Research Article

Approaches to Establishing National Diagnostic Reference Levels for Computed Tomography: A Systematic Review

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Abstract: ***Background:*** The international commission on radiation protection (ICRP) publican 135 recommends that Diagnostic Reference Levels (DRLs) should be tied to defined technical and patient parameters for the imaging task. Whereas for computed tomography (CT) examinations, DRLs are defined in terms of two established technical parameters namely, Volume-based Computed Tomography Dose Index ($CTDI_{vol}$) and Dose Length Product (DLP), a debate has ensued as to whether patient size, age and weight or clinical indication should be used as patient parameters. The objective of diagnostic reference levels (DRLs) is to assist in the optimisation of radiation dose to the patients while maintaining diagnostic image quality. It is generally accepted that each country requires having national DRLs to guide the practice of radiography regarding dose optimization as a prerequisite to good radiation protection practice. ***Objective:*** This review aimed to establish commonly used approaches to establishing national diagnostic reference levels for computed tomography. ***Methods:*** A systematic literature search in databases containing leading journals in radiography, radiology and medical physics was performed aided by the use of carefully selected search terms that relate to CT and DRLs. The literature search was achieved by the use of the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) flow chart. A total of 109 studies were screened out of which 54 were excluded and 55 sought for retrieval. After further assessment for quality, 20 studies were included in this study for review. ***Key Findings***: 95% of the studies in this review used $CTDI_{vol}$ and DLP as technical parameters indicating dose. 70% of the studies reviewed used patient size, age and weight while 30% used clinical indication as patient parameters. 30% of the reviewed articles did indicate that the surveys to establish NDRLs employed a retrospective approach, while 35% employed a prospective approach and 35% did not indicate whether survey approaches employed were retrospective or prospective. 40% of the reviewed articles indicated that quality control (QC) tests were performed on the CT units from which the dose indices were derived to establish NDRLs. However, 60% did not indicate whether the QC tests were done or not. ***Conclusion***: We found varying approaches to establishing National DRLs for CT. whereas there is general agreement in being compliant with ICRP to use the $CTDI_{vol}$ and DLP as technical parameters indicating dose, inconsistencies have been observed regarding the clinical parameters that are used in establishing NDRLs. This suggests that there is a need to standardise approaches employed in establishing them as a way of ensuring consistency and compliance with the requirements of the ICRP.

Keywords: Computed tomography, diagnostic reference levels, volume-based Computed Tomography dose index, patient parameters.

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1.0 INTRODUCTION

1.1 Background

Computed tomography (CT) is a widely used imaging modality which creates detailed images of anatomical structures with high spatial and temporal resolution and has played a paramount role in the management of diseases since its introduction (Hou *et al*., 2014). Its ability to produce cross-sectional and three-dimensional (3D) images which permit enhanced diagnosis of many pathogenic processes, versatility, accuracy, and non- invasiveness has been credited for the rapid increase in its use (Almohiy, 2014). The increase in the number of examinations has made CT one of the largest sources of medical exposure to radiation (Mettler Jr *et al*., 2009). Whereas a high radiation dose to the patient may cause a non-negligible lifetime risk of cancer, a low radiation dose however results in degraded CT images leading to misdiagnosis (Niu *et al*., 2016).

The protection of humans from the harmful effects of radiation in CT is governed by the principles of practice justification, dose optimisation and dose limitation (Roch *et al*., 2018). Critical to image quality and radiation dose is the principle of dose optimisation which implies that while the radiation dose is kept as low as possible, the image quality should not be compromised (McCollough *et al*., 2009). In order not to inhibit the potential benefits of exposure, the International Commission on Radiological Protection (ICRP) introduced the concept of Diagnostic Reference Levels (DRLs) in the 1990s as a dose optimisation tool (Drexler, 1998). The objective of DRLs is to assist in the optimisation of radiation dose to the patients while maintaining diagnostic image quality (Edmonds, 2009). It is generally accepted that each country requires to have national DRLs to guide the practice of radiography about dose optimization as a prerequisite to good radiation protection practice (Salama *et al*., 2017).

Approaches to establishing DRLs should involve the use of defined technical and patient parameters for the medical imaging task (Vañó *et al*., 2017). For CT examinations, DRLs are defined in terms of two established technical factors, namely, Volume-based Computed Tomography Dose Index ($CTDI_{vol}$) and Dose Length Product (DLP). The $CTDI_{vol}$ represents the average dose per slice, whilst the DLP reflects the total energy absorbed along the scan length and is the product of the $CTDI_{vol}$ and scan length (AAPM, 2008). A debate has ensued as to whether patient size, age and weight or clinical indication should be used as a patient parameter in establishing DRLs. According to Vañó *et al*., (2017), most surveys have used what is referred to as average-sized patients when setting up DRLs because the size of the patient plays a significant role in the determination of the amount of radiation to achieve adequate image quality for a given procedure. However, some countries are now establishing NDRLs based on clinical indications, arguing that for the same anatomical location, one could have different clinical indications requiring different imaging protocols that require different levels of exposure (Roch *et al*., 2020). This review, therefore, seeks to synthesise knowledge on common approaches in establishing NDRLs.

1.2 Key Concepts

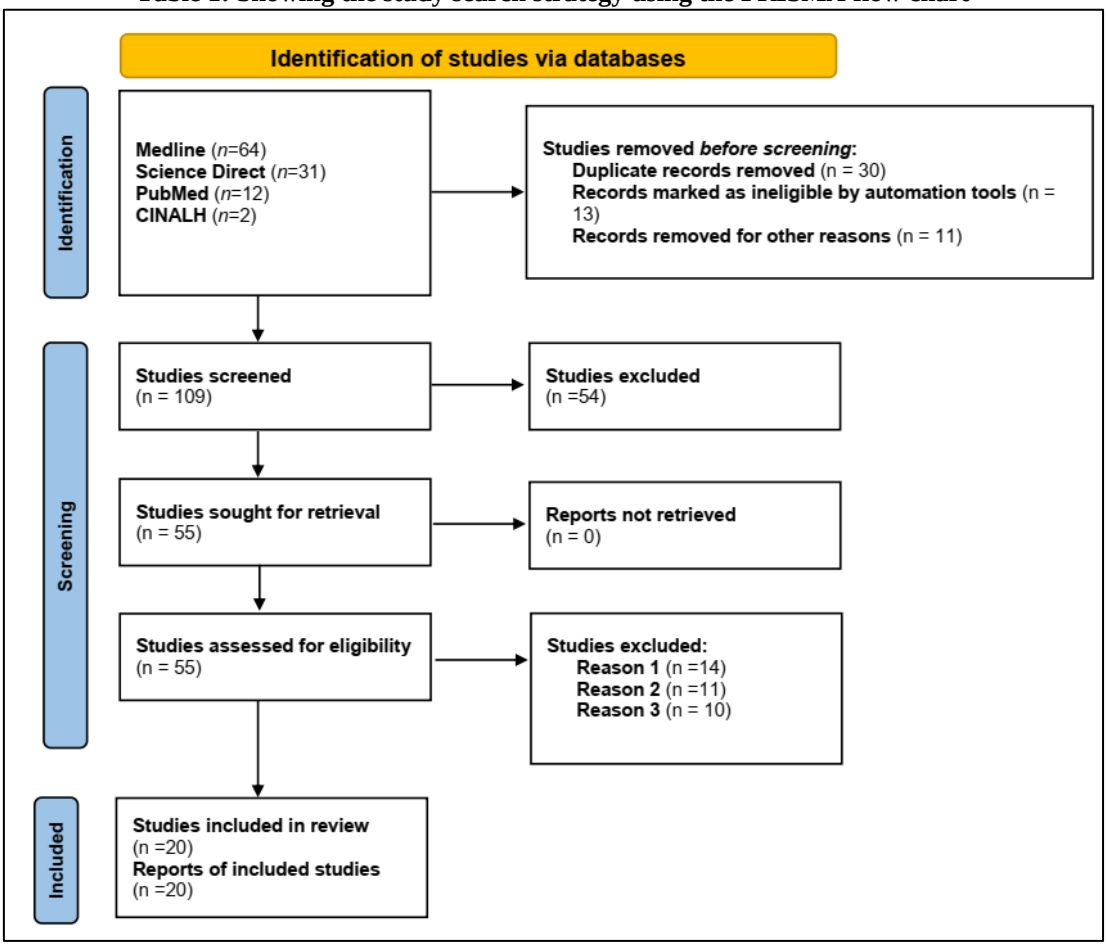
In a systematic review, key concepts related to the topics or components which the desired articles should address are discussed (Bramer *et al*., 2018). In this study, the key concepts included the following: Computed Tomography, Diagnostic Reference Levels, National Diagnostic Reference Levels, Indication-based Diagnostic Reference Levels and Size-specific dose estimates.

2.0 METHODOLOGY

2.1 Search Strategy

A systematic literature search in selected databases containing leading journals in radiography, radiology and medical physics was performed aided by the use of carefully selected search terms that relate to CT and DRLs. The literature search was achieved by the use of the Preferred Reporting Items for Systematic Reviews and Meta- analysis (PRISMA) flow chart as seen in Table 1 below. The PRISMA flow chart demonstrates the identification and screening process of the potentially eligible studies that will be included for analysis (Harris *et al*., 2014). The databases searched for literature included Medline, Science Direct, PubMed and CINALH as indicated in the PRISMA flow chart below.

Table 1: Showing the study search strategy using the PRISMA flow chart



2.2 Eligibility Criteria

The eligibility criterion for articles to be included in this review was derived by operationalising the PICO framework that was used to formulate the research question as follows:

Table 2: Showing eligibility criteria for study inclusion using the PICO framework

PICO	Inclusion Criteria	Exclusion Criteria
Population (CT Dose Indices)	DRL surveys using $CTDI_{vol}$ and/or DLP as indicators of radiation dose in CT.	DRL surveys based on phantom measurements.
	DRL surveys based on commonly done CT examinations i.e. Head, Chest and Abdomen/Pelvis.	DRL surveys that involve paediatric doses or other anatomical regions
Intervention (Patient parameters)	DRL surveys using patient parameters such Age, Weight and Sex.	DRL surveys based on phantom measurements.
Comparison (Clinical indication)	DRL surveys based on clinical indication.	DRL surveys based on phantom measurements.
Outcomes (DRL Values)	National DRL values based on third quartile $CTDI_{vol,}$ DLP and patients parameter or clinical indication.	Regional DRL Values.
		Local/institutional DRL Values
		National DRL surveys based on phantom measurements.

2.3 Study Selection

A stringent approach to selecting studies to be included in this systematic review was employed to ensure transparency in the process and the reliability of results. A two (2) step process was employed in which the first step involved the author screening titles and abstracts of studies retrieved from bibliographic searches. This was achieved by examining titles and abstracts, retrieving the full text of the relevant studies, examining the full text to determine eligibility and making the final decision on study inclusion. The second step involved two reviewers, independent of each other; reviewing and assessing the articles selected by the author for appropriateness and methodological quality,

in what is commonly referred to as conventional double screening (Waffenschmidt *et al*., 2019).

2.4 Quality Assessment of Selected Studies

The quality of the articles included in this review was determined by the use of the Joanna Briggs Institute (JBI) Critical appraisal tool. The JBI tool can provide systematic reviewers with approved methods of assessing the methodological quality of articles (Munn *et al*., 2020).

Data Extraction

The extraction of data from the studies selected for this review was done by two persons extracting data independently from each study to minimise errors and reduce the potential for bias. The data extracted from the selected articles included bibliographic details, dose indices, patient characteristics, anatomical site of examination, clinical indication per anatomical site, sample size, country of study, methodology used to establish drl values and scan technical parameters.

2.5 Synthesis and Data Analysis

Synthesis of the data extracted from the selected studies in this review involved combining the results of the studies included. The findings from the included studies were then summarised with reliable conclusions to be drawn based on the quality of the evidence.

3.0 RESULTS

This review aimed to establish the commonly used approaches to establishing NDRLs for CT based on surveys done to establish or update NDRLs in various countries. These included surveys using $CTDI_{vol}$ and DLP values as technical parameters indicating radiation dose, patient parameters such as patient size, weight and age and those based on clinical indication. As per ICRP guidance, all surveys in this review used $CTDI_{vol}$ and DLP as dose indicators while varying patient parameters were used to establish DRLs.

3.1 Data Extracted from the Included Studies

After a two-step study selection process, 20 articles were included in this review. Synthesis and analysis of data among others were based on the technical parameters, patient parameters, survey design methodology and whether or not QC tests were done in the establishment of NDRLs in these respective countries. The table below shows the various data extracted during this review.

Table 3: Showing the data that was extracted from the included studies

COUNTRY	YEAR	TECHNICAL PARAMETERS	PATIENT PARAMETERS	SURVEY DESIGN	DRL	SAMPLE	SITES	QC TEST DONE
Ireland	2012	$CTDI_{vol}$/DLP	Size	Prospective	3^{RD}	3305	30	No
Finland	2015	$CTDI_{vol}$/DLP	Clinical indication	-	3^{RD}	3600	57	No
Korea	2019	$CTDI_{vol}$/DLP	Age, weight	Prospective	3^{RD}	13,625	369	No
Switzerland	2010	$CTDI_{vol}$/DLP	Clinical indication	Prospective	3^{RD}	1647	179	Yes
Algeria	2020	$CTDI_{vol}$/DLP	Age, Weight	Prospective	3^{RD}	2540	18	Yes
Australia	2013	$CTDI_{vol}$/DLP	Age, weight	-	3^{RD}			No
Egypt	2017	$CTDI_{vol}$/DLP	Weight	Prospective	3^{RD}	3762	50	No
UAE	2020	$CTDI_{vol}$/DLP	Age, Weight	-	3^{RD}	240	3	No
Indonesia	2020	$CTDI_{vol}$/DLP	Size	Retrospective	3^{RD}			No
Nigeria	2018	$CTDI_{vol}$/DLP	Age, Weight	Retrospective	3^{RD}		36	No
Japan	2018	$CTDI_{vol}$/DLP	Age, Weight	-	3^{RD}		3000	No
Austria	2018	DLP	Age, clinical indication	-	3^{RD}	13,237	179	Yes
China	2018	$CTDI_{vol}$/DLP	Age	Retrospective	3^{RD}	164,073	8	No
France	2019	$CTDI_{vol}$/DLP	Clinical indication	Retrospective	3^{RD}	6610	86	No
Iran	2015	$CTDI_{vol}$/DLP	Age, weight	-	3^{RD}		24	Yes
Italy	2013	$CTDI_{vol}$/DLP	Age, weight	Prospective	3^{RD}	5668	65	Yes
Serbia	2014	$CTDI_{vol}$/DLP	Weight	-	3^{RD}		6	Yes
Ghana	2021	$CTDI_{vol}$/DLP	Clinical indication	Prospective	3^{RD}	3690	25	Yes
Qatar	2020	$CTDI_{vol}$/DLP	Clinical indication	Retrospective	3^{RD}	896	7	No
Uganda	2022	$CTDI_{vol}$/DLP	Age	Retrospective	3^{RD}	574	7	Yes

The articles included in this review were those done to develop NDRL within the past 15 years. The distribution of the years in which these national DRLs were established is shown in the figure below.

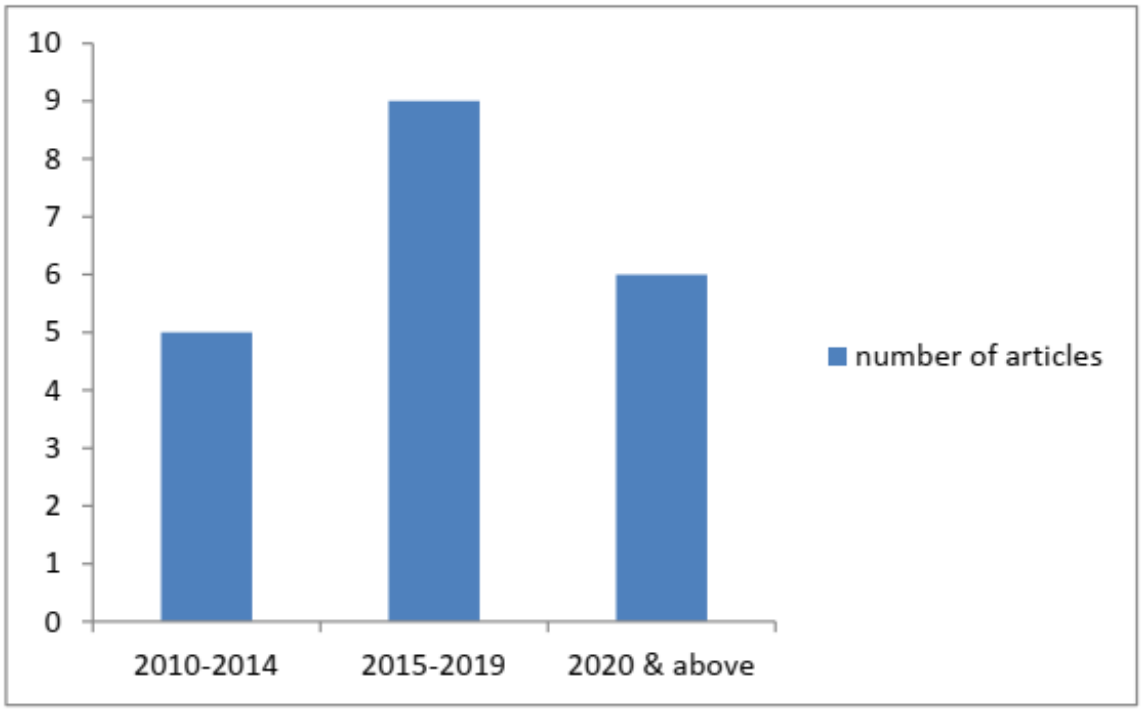


Figure 1: showing the years of publication of the DRLs in this review.

3.2 Technical Parameters used to Establish NDRLs

The appraisal of the articles included in this review revealed that almost all of the surveys (*n* 19, 95%) used to establish NDRLs in these respective countries used a combination of $CTDI_{vol}$ and DLP. Only one country (*n* 1, 5%) used only the DLP as a technical parameter in the establishment of NDRLs.

3.3 Patient Parameters used to Establish NDRLs

All the 20 articles in this review indicated that the common CT examinations used to establish DRLs were head, chest and abdomen while others among the 20 articles included other examinations such as the neck, pelvis as standalone or a combination of abdomen and pelvis. Most of the countries (*n*-14, 70%) had NDRLs established based on patient parameters such as size, age, weight and gender of the patient as patient parameters while the rest (*n*-6, 30%) had their NDRLs established based on the clinical indication of the patient. The most common clinical indications used to establish IBDRLs included cerebrovascular accident (n-4, 67%), trauma (n-4, 67%), tumours (n- 3, 50%), sinusitis (n-2, 33%) for head scans and tumours (n-1, 17%), pulmonary embolism (n-2, 33%) and lung infections (n-1, 17%) for the lung scans while for the abdominal scans, tumours were (n-3, 50%), urolithiasis (n-3, 50%) and infections (n-1, 17%).

3.3 Survey Methodology

A review of the methodology used to establish NDRLs by the articles included in this review established that most of the articles (n-14, 70%) did indicate the sample size of CT images included in the survey while the others (*n*-6, 30%) did not. The inclusion of the total number of sites or CT units that participated in the establishment of national DRLs for each country was such that most articles (*n*-18, 90%) did indicate the exact number of participating sites while the rest (*n*-2, 10%) did not indicate. Of the 20 articles reviewed, 6 of them (*n*-6, 30%) did indicate that the survey to establish NDRLs employed a retrospective approach, while 7 (*n*-7, 35%) employed a prospective approach and the rest (*n*-7, 35%) did not indicate whether that survey approach was retrospective or prospective.

3.4 Quality Assurance Tests

Eight (8) of the included articles (*n*-8, 40%), clearly indicated that quality control tests were performed on the CT units from which the dose indices were derived to establish NDRLs. However, in the rest of the other articles (*n*-12, 60%), it was not indicated or even mentioned whether the QC tests were done or not.

4.0 DISCUSSION

The ICRP publication 135 recommends that NDRLs should be tied to defined technical and patient parameters for the imaging task. This requirement implies that approaches to establishing NDRLs should incorporate CT technical parameters indicating dose and patient parameters for each imaging task. According to Vañó *et al*., (2017), the precise dosimetric quantity to be utilised in the development of DRLs should be determined by the organisation setting the DRL. However, the ICRP recommends that both $CTDI_{vol}$ and DLP should be used in patient surveys when setting DRL values. All studies in this review were those that used $CTDI_{vol}$ and DLP as technical parameters to establish NDRLs with 95% using both $CTDI_{vol}$ and DLP and only 5% using DLP only. This was suggestive of elevated levels of the adoption of recommendations by ICRP.

Nevertheless, there were inconsistencies in the patient parameters that were used with 70% of the surveys using average patient size, age and weight and 30% using the clinical indication as patient parameters. The selection process of patient parameters to be included in the survey when establishing DRLs is an important aspect. Patient size in CT plays an important role in the determination of the amount of radiation required to achieve adequate image quality for a given procedure (Samei and Christianson, 2014). It, therefore, follows that surveys that establish NDRLs should explicitly specify how this process was carried out. For articles in this review, there is variability in reporting criteria used in selecting patient parameters that are utilised in the survey to establish NDRLs; with some articles reporting patient average size (*n*-2, 14%), weight (*n*-2,14%), a combination of age and weight (*n*-8, 68%) and age only (*n*-2, 14%) as selection criteria.

Quality control tests are essential to monitoring scanner performance and are employed for clinical CT to optimise patient safety and the reliability of dosimetric data (Mambrini *et al*., 2022). Whereas it is a requirement that quality control tests should be performed on the CT unit before the collection of data, fewer studies in this review (n-8, 40%) indicated that the QC tests were done while the rest (n=12, 60%) did not explicitly indicate if QC tests were done or not. This review brings to the fore lapses in reporting approaches to establishing NDRLs characterised by omission to carry out or report important steps such as quality control protocols.

5.0 CONCLUSION

This review has revealed varying approaches to establishing National DRLs for CT. Whereas there is general agreement in being compliant with ICRP to use $CTDI_{vol}$ and DLP as technical parameters indicating dose, inconsistencies have been observed regarding the clinical parameters that are used in establishing NDRLs. Most surveys use patient parameters such as size, age and weight in establishing NDRLs as pposed to clinical indications. Further, there is a common pattern in most reviewed articles to not indicate whether QC tests were done or not when setting up NDRLs.

6.0 RECOMMENDATIONS

To derive uniform benefits of having National DRLs as a dose optimisation tool, there is a need to standardise approaches employed in establishing them as a way of ensuring consistency and compliance with the requirements of the ICRP Publication 135.

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