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Diagnostic Reference Levels (DRLs) in Digital Mammography: A Systematic Review

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Abstract

DRLs are considered an effective tool that can be used to optimization of patients protection in the medical exposure for diagnostic and interventional procedures. Screening mammography facilitates the early detection of breast cancer and reduces the mortality rate of women from breast cancer. The utility of giving very high detail resolution or image sharpness and the effectiveness of Digital Mammography (DM) for imaging micro-calcifications and minor abnormalities that may reveal early breast cancer are all features of DM. DM is used in screening mammography. The establishment of DRLs in digital mammography helps in dose optimization in screening mammography. This study was performed to review the present literatures on Diagnostic Reference Levels (DRLs) which are useful in optimizing dose to breast in digital mammography. The literature search of Google Scholar, PubMed was done to find the studies that have established (within 2010 -2021) DRLs for digital mammography. The founded 12 literature which established DRL in digital mammography; 3 studies based on the phantom, 6 in clinical (patients), and 3 in both methods were evaluated. The methodologies and data vary each other. The DRLs values are between 0.69 to 2.9 mGy. The mean AGD for CC and MLO projections is between 0.98 to 2.2 mGy and 1.11 to 2.5 mGy respectively for ten studies. There are no variations in DRLs related to the age and Compressed Breast Thickness (CBT) in digital mammography found in the nation in this study. But the mean AGD of MLO projection is higher compare to CC projection. The DRLs in digital mammography have nation wise changes. Establishment of national DRLs for digital mammography is essential in radiation protection of digital mammography.

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Introduction

Radiological protection should be applied to all diagnostic, screening and therapeutic medical practices where ionizing radiation is used to expose the patients. Even low radiation doses are utilized in medical procedures; stochastic effects (cancers and hereditary effects) are possible to be occurred with that radiation. The essential components of radiation protection in medical practices are Justification (analysis of risk-benefit ratio to the patient), optimization (all responsible steps taken to adjust the protection) and dose limit (limit should be applied to the dose for all individuals) [1]. There are significant amount of radiation protection programs based on the above three components carried out in every radiological departments [2].

Diagnostic Reference Levels (DRLs) were introduced by the International Commission of Radiation Protection (ICRP) in their publication 73, 1996 as a parameter which helps in quality control, dose-comparison, optimization and limitation of variations in the institutional, regional and national doses. It has defined DRLs as follows.

"A form of investigation level, applied to an easily measured quantity, usually the absorbed dose in air, or tissue-equivalent material at the surface of a simple phantom or a representative patient" [1].

DRLs are considered an effective tool that can be used to optimization of patients protection in the medical exposure for diagnostic and interventional procedures. Also DRLs could be considered an application of principle called ALARA (as low as reasonably achievable) which is used to optimize the radiation to patients in medical radiation practices. DRLs are not dose limits or dose constrains. It has no boundary line to separate the process which is good and which is bad. But DRLs are the indicator levels of doses to the patients for a particular radiological procedure. The main purpose of determination of DRLs is the comparison of detected DRLs value with previous DRLs value as well as other (institutional, regional and national) DRLs value [3]. The time-to-time updates of DRLs are required to determine the differences in doses with time. DRLs are varied with patients' factors and procedural factors. DRLs help to identify what are the protocols that need optimization [2,3,4,5].

There are four terms of DRLs defined as-follows by the International Commission on Radiological Protection (ICRP), in Publication 135, 2017. Those are DRL, DRL quantity, DRL value and DRL process [2].

DRL - A form of investigation level used as a tool to aid optimization of protection in the medical exposure of patients for diagnostic and interventional procedures.

DRL quantity - A commonly and easily measured or determined radiation metric that assesses the amount of ionizing radiation used to perform a medical imaging task.

DRL value - An arbitrary national value of a DRL quantity, set at the 75th percentile of the distribution of the medians of distributions of DRL quantity obtained from surveys or other means.

DRL process - The cyclical process of establishing DRL values, using them as a tool for optimization, and then determining updated DRL values as tools for further optimization.

Image quality or diagnostic quality should be maintained at the same time keeping the patient exposure "As Low as Reasonably Achievable" (ALARA principle). The 50th percentile of the national DRLs is considered as the image quality assessment factor. If the measured DRL value is less than 50th percentile of national DRLs value, it is counted as image quality has degraded. So, DRLs can be used in both patient dose optimization and image quality optimization processes on radiology procedures [2].

Mammography is one of the radiological procedure which is used for imaging and some interventional procedures of the breast. Screening mammography facilitates the early detection of breast cancer and reduces the mortality rate of women from breast cancer [1,6]. Digital mammography (DM) is a type of mammography that produces high-resolution images of the breast. The utility of giving very high detail resolution or image sharpness, as well as the effectiveness of DM for imaging micro calcifications and minor abnormalities that may reveal early breast cancer, are all features of DM. Improved contrast resolution, magnification, and orientation brightness are all possible with DM. DM is more sensitive in detecting cancer, with no increase in the false positive rate in contrast to conventional [7]. In digital mammography, DICOM images are the final achievement which gives quantitative and qualitative data about the patients as well as the procedure. DICOM-"Digital Imaging and Communications in Medicine" is a definition for how image data, metadata, and associated information objects are stored in a binary format and sent across computer networks [8].

Breast tissues are more radiosensitive than fatty tissue or skin. Irradiation of the breast while screening mammography can cause to induce breast cancer [9]. Generally lower exposure factors (25-35kVp) are used and applying breast compression are the specific mammographic techniques which are preferred to reduce the dose to the patient (breast) in mammography [10]. In standard mammography centers, they have established, maintained and updated Quality Assurance (QA) program which optimizes the quality of procedure (to produce the high-quality images) and optimize the patient doses [6]. There are three personals and their own responsibilities to be carried out in a mammography QA program. The personals are the radiologist, medical physicist and radiological technologist. The responsibilities of the medical physicist in mammography are not only related to equipment performance as well as include image quality assessment, operator safety and patient dose evaluation. One of the QC test that should be performed by medical physicists is breast entrance exposure, AEC (automatic exposure control) reproducibility, average glandular dose and radiation output rate testing [10,26].

DRL of mammography is the reference value of dose which is the 75th percentile of the distribution of Average Glandular Doses (AGD). The AGD is the basic quantity that express the risks to the breast tissue [1,11]. Incident air KERMA (k_i), entrance surface air KERMA (k_e), and the conversion coefficient were used to estimate the mean glandular dose. Both incident air KERMA and AGD depend on the beam quality, the thickness of the breast and the breast composition. X-ray beam quality depends on target/filter combination, tube voltage and HVL (half value layer) of x-ray set. So, DRL of mammography depends on above all patients and technical (machine) related factors. When defining the DRL for mammography, have to consider all above factors and should define them. Mammographic DRL can define using both clinical (patients) mean and phantom model [12,13].

DRLs for mammography examination have been established in a number of countries around the world, but many others have yet to do so. This study conducted a literature review on measured DRLs in digital mammography and approaches for establishing them. The aim of this review was to compare those DRLs values, approaches and identify the variations in methodologies. In Sri Lanka, there was no established national DRLs value in mammography. So far, only one paper has been published related to DRLs in digital mammography. The further approach of this study is to try to analyze a method in establishing national mammographic DRLs in Sri Lanka which could assist in the evaluation of the local practice's performance as well as efforts to enhance radiation protection.

Materials and method

Method

The study was carried out using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Methodology (PRISMA) [27]. The literature search of Google Scholar, PubMed was done to find studies that have established DRLs for digital mammography. The search phrases (DRLs or Diagnostic Reference Levels or Average glandular dose) and (Mammography or Digital mammography) were utilized. A search filter was employed to limit the results to specified publication language, publication year and following inclusion criteria. The selected publication language was the English language, the literatures published from 2010 to 2021 were selected and other inclusion criteria were as follows.

Inclusion criteria

Literature which has free full-text access through the Google Scholar and PubMed were initially screened via the title and the abstract for full text review. The full-text review included only abstracts that explored AGDs in mammography. Articles that examined DRLs (institutional or regional or national or global) in digital mammography or both digital and conventional (fill-screen or computerized) mammography were included in this study. Articles which provided data from phantoms or patients were independently considered for inclusion in the review.

Exclusion criteria

Articles which were not published in the English language, not published from 2010 to 2021 and had no free full-text access were excluded. After full-text review, though they explored AGDs in mammography, the purpose of those studies were not towards the DRLs were excluded from the review. Literatures which have not considered about digital mammography were excluded. Literature which has analyzed DRLs for many radiographic procedures like computed tomography, fluoroscopy and interventional procedures were eliminated from this review.

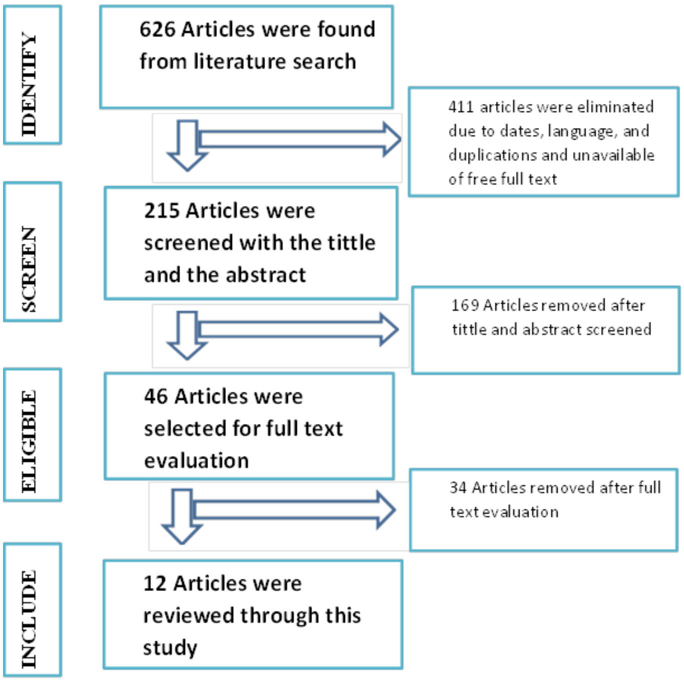

Figure 1: Flow of literature selection through data bases.

Results

A total of 626 articles were found using the combined search strategy: 317 from Google Scholar and 309 from PubMed. After the initial screening did base dates, language and full-text access, 250 citations were eliminated and 376 were screened for duplications. After all above processes were done, 215 were screened with tittle and abstract; 46 articles were deemed eligible for full-text evaluation. 34 papers were removed after the full-text assessment because they did not create DRLs for digital mammography nor had no clinical data. The systematic review contained a total of 12 papers in the end.

There are 4 studies from Asia [14,15,16,17] 3 from African [18,19,20] 3 from Europe [21,22,23] and one each from Australia [24] the Chile [25].

Table 1: The summarized details of 12 literature which were reviewed in the study.

Country	Author and year	Type of the defined DRLs	DR or both DR and CR/FC	Patients or phantoms	Number of machines
Australia (Aus)	David L. Thiele, et al. 2011	Regional	Both DR and CR	Phantom	54 (27 DR and 27 CR)
Norway (Nor)	Hauge I.H.R., et al, 2013	National	DR	Patient or phantom	26 (DR)
Chile (Chil)	Leyton F, et al, 2018	Regional	Both DR and CR	Phantom	6 (2 DR and 4 CR)
Portugal (Por)	Dos Reis C.S., et al, 2018	National	Both DR and CR	Patients or Phantom	38 (25 CR and 13 DR)
Greece (Gre)	Lekatou A., et al, 2019	Institutional	DR	Patients	1 (DR)
China (Chin)	Sci, 2019., et al, 2019	National	DR	Patients	8 (all DR)
Qatar (Qat)	Al Naemi H., et al,2020	National	DR	Patients or Phantom	3 (DR)
Turkey (Tur)	Parmaksiz A., et al, 2020	National	All DR,CR and SF	Patients	
Serbia (Ser)	Rafajlovic S., et al, 2020	National	All DR,CR and SF	Phantom	148 (16 DR, 72 CR, and 60 SF)
Palestine (Pla)	Krash R.M.R.A., et al, 2020	Institutional	Both DR and CR	Patients	2 (1 DR and 1 CR)
Ghana (Gha)	Dzidzornu E., et al, 2021	National	DR	Patients	3 (all DR)
Sudan (Sud)	Suliman I.I., et al, 2021	National	All DR,CR and SF	Patients	8 (4 DR, 2 CR, 2 SF)

Tables 1: Outline the major characteristics of the studies reviewed. 3 of the 12 studies used phantom data, 6 used patient data, and 3 used both. Five literatures were based on studies which have been done using only Digital Radiography (DR) mammographic machines and rest of the studies have been done using all DR, Computed Radiography (CR) and SFM (Screen-Film Mammography) techniques. Studies which have followed different strategies to measure the DRLs, they have compared final results for each strategy. In Table 1, a summary of strategies are included. Also from these 12 studies, 2 literatures have established the institutional DRLs, 2 literatures have established the regional DRLs and the remaining 8 were done for the establishment of national DRLs. Patient studies have an advantage over phantom studies in that they provide a more realistic and thorough assessment of doses supplied to people of various age, breast sizes and compositions.

Table 2: Shows the number of patients and the number of projections of 9 studies which have used patient details to establish DRLs in mammography.

Country	Number of patients	Number of views
Nor	1325	
Por	2121	8484
Gre	300	
Chin	1828	
Qat	150	600
Tur	6309	25624
Pal	200	800
Gha	979	3916
Sud	247	988

Table 2. Shows the number of patients and number of views for particular studies used during their research where established the DRLs in clinical means. At least 150 patients have been used for every study and a large amount of patients used is 6309 in a study done in Turkey (Bulur et al., 2020). Each of the studies has used data from 4 views (right and lateral, CC and MLO) in mammography.

A total of 9 patient studies exploring DRLs were examined (Table 3), with data collection techniques and patient parameters varying once again. Mean values of age (in years) and compressed breast thickness (CBT in mm) of patients for particular studies which have been mentioned in their studies have summaries with the technical parameters tube voltage (kVp) of their studies. Also the mean values of dose parameters (ESD in mGy) were enlisted for the same studies. There are variations in the methodology of establishing DRLs throughout this review. Literature from Australia, Greece, China, Turkey, Palestine, Ghana, Sudan has established the 75th value of the distribution of AGD values. Articles which have done in Greece, Turkey, Palestine and Ghana have published the ESD (entrance surface dose) values in their study.

The DRL value of the study done in Norway by [23] is 1.44mGy which is defined as the 75th percentile of the distribution of the mean AGD of MLO projections in CBT range 55-65 mm. The DRL value of literature published in Palestine by Krash R.M.R.A., et al, 2020 is established as 1.24 which is the 75th percentile of mean AGD distributions of MLO projections in CBT range 60 -70 mm.

Table 3: The summarized patients and technical data for 9 literatures.

Country	Age(yrs)	CBT(mm)	kVp	ESD-mean (mGy)	AGD-mean	AGD-75th	DRLs mean DRLs - 75th DRLs - 95th
Norway		(55-65)	30 (29-30)		2.5		Mean = 0.69-2.11 75th = 1.44 95th = 1.98
Portugal	45-69	52.25 (17-105)	29 (23-38)		1.35		Mean = 1.35
Greece	40-80	56.3 (26-99)	29.6 (26-35)	5.01	1.25	1.51	Mean = 1.25 75th = 1.51 95th = 1.86
China	46	46+12 (15-86)	28.9+1.8 (25-33)		1.1	1.5	
Qatar	20-76	CC=60.3+13.9, MLO=67.9+12.9	30.2 (26-36)		CC= 2.2 MLO=2.5		
Turkey	50-64	49.2 (15-104)	28.5 (23-45)	CC=7.4 MLO=9.1	CC=1.6 MLO=1.9	CC=2.2 MLO=2.6	CC=2.34 MLO=2.9
Palestine	(47) 40-64	61.32 (23-100)	31.1 (25-35)	5.2	1.06	1.21	Mean = 1.10 75th = 1.24 95th = 1.64
Ghana	54 (35-87)	40+14, (3-100)	27.8+1.4 (23-32)	6.2	1.9	2	Mean = 2
Sudan	29	CC=38 MLO=44	31		CC=1.08 MLO=1.11	4.44	Mean = 2.19 75th = 4.44

Table 4: Mean AGD (mGy) and mean age (years) in in digital mammography of 9 literatures reviewed.

Mean Age Range	AGD (in mGy) of countries								
	Chin	Gha	Gre	Nor	Pal	por	Qat	Sud	Tur
<49								1.08, 1.11	
40-45									1.7-1.9
46-50	1.3				1.06		2.2-2.5		
51-55		1.9				1.35			
56-60			1.25						1.6-1.9

Table 4 shows the DRLs distribution of 8 studies among those selected 9 studies. The study done in Norway by [23] is not mentioned average age in their study. While looking at other eight studies could see mean age has distributed from 29 years to 56 years. The lowest mean age is 29 years in the study done in Sudan [20]. The mean AGD for this study is 1.08mGy and 1.11mGy for CC and MLO projections respectively. The dose values are the second lowest values among others. This study has done for both symptomatic and screening mammography. Age 29 is a considerably lower value for screening mammography. 2 studies done in Greece by [21] and in Turkey by have the highest mean age 56 years in their study. 3 literatures show the mean age in range of 46 years to 50 years.

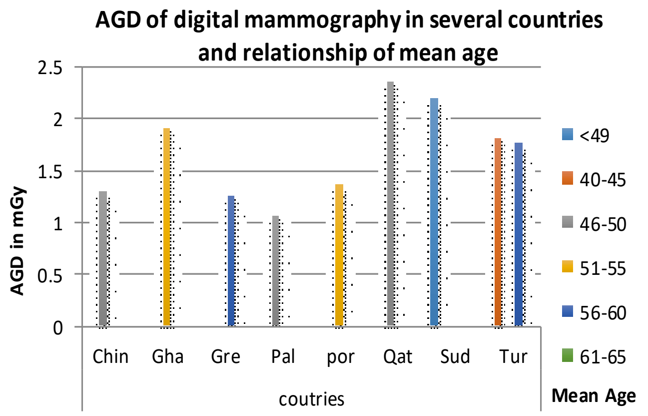

Figure 2: The graph shows variation of mean AGD of countries with mean age.

Figure 1: Graph Show the distribution of mean AGD with mean age ranges for 8 countries. Whether some literature have same mean age ranges; their mean AGDs have significant variation. The studies which have done in Turkey have performed a study establishing DRLs for two age groups and have published 2 mean AGD for each age group separately.

In the next step, the variations of observed AGDs are discussed with patient Compressed Breast Thickness (CBT). Table 5 shows ranges of mean CBT in these studies varying in between 38mm to 68mm. The lowest mean CBT value was shown in a study done in Sudan [20] where showed the lowest mean age for the study. The mean AGD for the 38 mm CBT is 1.08mGy which is second-lowest mean AGD value. The lowest mean AGD dose 1.06mGy is in 61-65 mm mean CBT range from the reviewed literature in Palestine by while other mean AGD value 2.2mGy from Qatar by [15] is in the same CBT range 61-65 mm. The other 2 literature have the mean CBT value in the same range (40- 45 mm), one by [17] China with mean AGD 1.3mGy and another from Turkey by with mean AGD 1.8mGy. Another 2 studies in 40-45 mm mean CBT range having mean AGD 1.11mGy and 1.9mGy for Sudan [20] and Ghana [18] respectively. There is considerable variation in each 2 mean AGD values in the same mean CBT ranges as figure 2 graphs shows.

Table 5: Mean AGD variation with mean CBT.

Countries	Mean Compressed Breast Thickness (CBT) in mm						
	<40	40-45	46-50	51-55	56-60	61-65	66-70
Por				1.35			
Gre					1.25		
Chin			1.3				
Qat						2.2	2.5
Tur			1.8				
Pal						1.06	
Gha		1.9					
Sud	1.08	1.11					

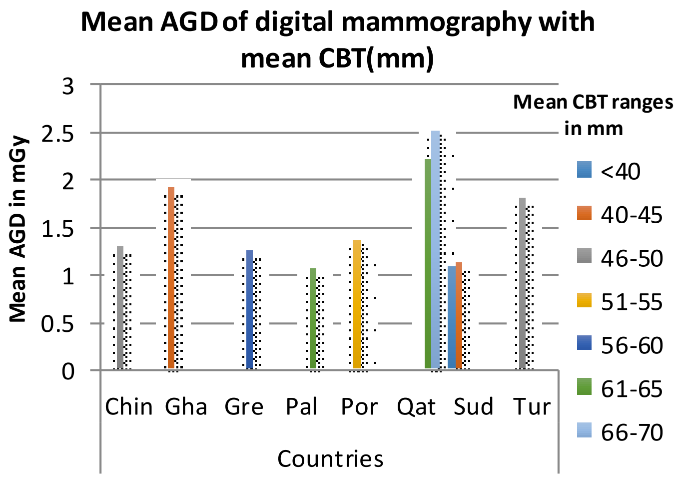

Figure 3: The Graph shows variation in mean AGD with mean CBT.

10 of 12 (83.33%) studies which were reviewed have mentioned mean AGD values for each CC and MLO separately. The study was done by Parmaksiz A., et al, 2020 have established DRLs only for CC and MLO values. Mean AGDs for CC projection and MLO projection are in between 0.98mGy to 2.2 mGy and 1.11mGy to 2.5 mGy respectively. In every literature the mean AGD value for MLO projection is higher than for CC projection (shown by graph 3). The dose values for CC and MLO projections and their variation are shown in table 6. The AGD variation for CC and MLO is in the range of 0.03-0.4mGy. The lowest variation 0.03mGy is shown in literature in Sudan by [20]. The highest variation 0.4mGy is in the literature done in Ghana by [18].

Table 6: The meann AGD for CC and MLO projection in mammography for different countries.

View	Mean AGD (in mGy) of Digital Mammography for CC and MLO views in reviewed Countries									
	Nor	Por	Gre	Chin	Qat	Tur1	Tur 2	Pal	Gha	Sud
CC	1.23	1.54	1.18	1.27	2.2	1.7	1.6	0.98	1.6	1.08
MLO	1.35	1.68	1.32	1.33	2.5	1.9	1.9	1.13	2	1.11
Variation	0.12	0.14	0.14	0.06	0.3	0.2	0.3	0.15	0.4	0.03

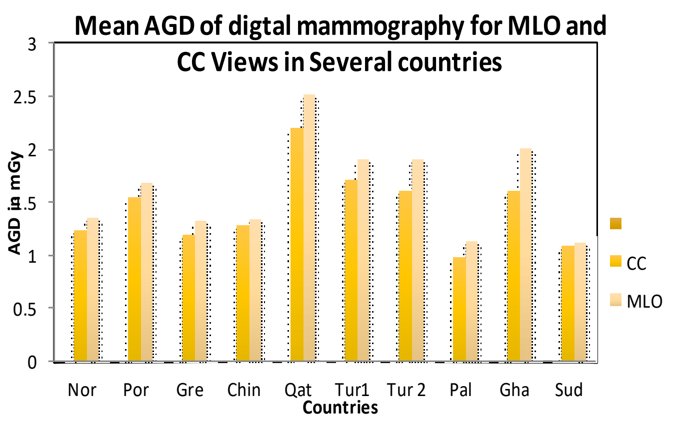

Figure 4: The graph shows the mean AGD for CC and MLO projection in mammography.

Discussion

The absence of standardization and a globally accepted process for determining DRLs makes it difficult to compare doses across countries. International comparisons have revealed disparities that are frequently highlighted by authors for all reviewed 12 studies that have conducted different strategies. The flow of DRLs distribution shows some same variation within studies. The studies have tried to establish DRLs related to particular institutions, regions and nations.

Table 4 and graph 1 show the mean AGD or DRL distribution with age among countries. But there cannot be found that direct proportion between DRL and age from this review. In the same age range there are several mean AGD values. There is no any increment or discrete of mean AGD with age.

Table 5 and graph 2 show the relationship of mean AGD with CBT. In this parameter also desn't show a direct proportion between AGD and CBT globally. In the same CBT range there are significant variations of mean AGD for different nations.

According to this study evaluation of the DRL along with one parameter like age and CBT is difficult. To see the variations of DRL with one parameter studies should have followed same protocol. In this review, globally conducted articles which were proceeded different methodologies are reviewed. Most of the articles have published their data related to technical parameters, patient parameters.

When evaluating the DRLs with respect to the CC and MLO projection; there are higher values for MLO projection compared to CC projection in all studies which have established AGD for CC and MLO projection.

DRLs are considered an effective tool which can be used to optimization of patients protection in the medical exposure for diagnostic and interventional procedures. Since IAEA introduced DRL in its publication 73 in 1996, so many countries have tried to establish the institutional, regional and nation DRL for digital mammography worldwide. The comparison of detected DRL with others helps identify the deviations and errors of the procedure.

Conclusion

The establishment of the DRLs for digital mammography is becoming essential part of quality control process in a mammography unit across the world. Publication of the articles that examined DRL provides unopened knowledge to some countries that have not explored the DRLs procedures yet in their radiological practices. The mammographic DRL values are varies from nation to nation. The establishment of national DRL in mammography is crucial for radiation protection in mammography screening. Effort should be taken to establish and maintain the national mammographic DRL in Sri Lanka.

Suggestion

1. Establish institutional and regional DRL in digital mammography and then establish national DRL for digital mammography in Sri Lanka.
2. Update, and maintain the established DRLs, and use the DRLs to identify errors/requirements in dose optimization (quality control) while comparing them with other international standards.
3. Recruit, educate the required professionals, and practice for quality control in radiological procedures.

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