CURRENT TRENDS AND LIMITATIONS IN ESTABLISHING DIAGNOSTIC REFERENCE LEVELS(DRLs): A GLOBAL PERSPECTIVE

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ABSTRACT

Diagnostic Reference Levels (DRLs) are systematic and scientific protocol used for identifying situations where patient's doses are high in diagnostic radiology and nuclear medicine examinations. They are suggested action levels in which a facility can check it's performance and see if achievable doses provide adequate images of diagnostic yield. The study systematically appraise and document the current trends and limitations of diagnostic reference levels and further explains the need to project a way forward by delving and foreseeing into a new concept of acceptable quality dose which addresses the limitations of Diagnostic reference level.

Key words: Diagnostic Reference Levels, Dose, Patients, Adequate Quality Dose, Radiology, Examination

INTRODUCTION

Establishing DRLs is important because it forms a comprehensive, concise and powerful tool for optimizing radiation protection of patients [1]. Diagnostic reference level is intended for use as a simple test for identifying situations where the level of patient dose or administered activity is unusually high. If it is found that procedures are consistently causing the relevant diagnostic reference level to be exceeded, there should be a local review of procedures and the equipment in order to determine whether the protection has been adequately optimized. If not, measures aimed at reduction of dose should be taken [2].

Diagnostic reference levels are subject to professional judgment and do not provide a dividing line between good and bad practice. It is inappropriate to use them for regulatory or commercial purposes. Diagnostic reference levels apply to medical exposure, not to occupational and public exposure. Thus, they have no link to dose limits or constraints. Ideally, they should be the result of a general optimization of protection.

In practice, this is unrealistically difficult and it is simpler to choose the initial values as a percentile point on the observed distribution of doses to patients. The values should be selected by professional medical bodies and reviewed at intervals that represent a compromise between the necessary stability and the long-term changes in the observed dose distributions. The selected values will be specific to a country and or region [2]. Diagnostic reference levels are not the suggested or ideal dose for a particular procedure or an absolute upper limit for dose. Rather, they represent the dose level at which an investigation of the appropriateness of the dose should be initiated. In conjunction with an image quality assessment, a Qualified Medical Physicist should work with the Radiographer to determine whether or not the required level of image quality could be attained at lower dose levels. Thus, reference levels act as "trigger levels" to initiate quality improvement. Their primary value is to identify dose levels that may be unnecessarily high - that is, to identify those situations where it may be possible to reduce dose without compromising the required level of image quality. In keeping radiation dose to patients to a minimum in hospitals, it is needful to be able to estimate prior to medical examination the dose to patients as a function of radiographic exposure parameters [3].

Monitoring of patients during the examination has been a major way of assessing radiation dose received in diagnostic and therapeutic radiology [4]. For the purpose of optimization in radiation protection, dose delivered to patients during diagnosis is studied with assessment of image quality [5]. This is a common practice in many parts of the world who present with clinical cases requiring x-ray examination which are often times not properly done and this is largely due to lack of facilities and suitable qualified personnel. As a result, there is no sufficient information about patient's radiation dose [6].

Radiation dosimetry is required to assess the risk associated with x-ray exposure and to inform medical radiation professionals of the levels of exposure received [7]. Patient dose measurement is an integral part of optimization process [8]. Quality management of any use of medical x-ray imaging should include monitoring of radiation dose [7]. A major goal of the quality program for all forms of x-ray imaging is to minimize radiation risk without degrading clinical performance [7]. In order to interpret correctly the relationship between a change in the numerical value of a quantity used as a diagnostic reference level and the corresponding change in patient tissue doses that determine the relative patient risk. Establishment of DRLs for pediatrics may require some adjustments and modifications so as not to compromise the medical imaging task. It requires detailed assessment of procedures and protocols taking into consideration the guidelines established by international organizations.

Objective of Diagnostic Reference Level

The objective of Diagnostic Reference Level (DRL) is to avoid excessive radiation to the patient that does not contribute additional clinical information and value to the medical imaging task [14].

Uses of a Diagnostic Reference Level

Diagnostic Reference Level is used;

a) To improve a local regional or national distribution of observed results for a general medical imaging task, by reducing the frequency of unjustified high or low dose values;

b) To promote attainment of a narrower range of values that represent good practice for a more specific medical imaging task; or

c) Typically, diagnostic reference levels are used as investigation levels (as a quality assurance tool), they are advisory and not a dose limit, therefore should not be applied to individual patients.

d) The application of a Facility Reference Levels (FRLs) is for the local imaging facility to establish a reference dose for their common imaging protocols that can be used for internal and external comparison.

e) DRLs can also be used for international comparative dosimetry.

Applications of DRLs

DRLs, together with an optimization process, help reduce unnecessary patient doses and the consequent radiation risks.

A Diagnostic Reference Level can be used to:

i. improve local, regional, or national distributions of observed doses for a general medical imaging task, by reducing the frequency of unjustified high or low dose values

ii. promote a narrower range of doses that represent good practice for a more specific medical imaging task

iii. promote an optimum range of doses for a specified medical imaging protocol

iv. provide a common dose metric for the comparison of FRLs between facilities, protocols and modalities

v. assess the dose impact of the introduction of new protocols

vi. provide compliance with the relevant state and territory regulatory requirements Appropriate local review and action is required when the doses observed are consistently outside the selected Diagnostic reference level, unless clinically justified. However this elevated dose with clinical justification should be an exception rather than the norm across multiple DRLs.

Deriving Diagnostic Reference Levels

Diagnostic reference levels will be taken from the third quartile (75^{th} percentile) readings of the distribution of mean doses from different radiological examination values obtained. Following standard protocol for dosimetric data acquisition established by International Atomic Energy Agency [14].

Step 1

Mean Thermoluminescent Dosimeter values and or Dose Area Product ($mGy.cm^2$) values for conventional Radiography and Fluoroscopy, Computed Tomography Dose Index (mGy) and Dose Length Product ($mGy.cm$) values for Computed Tomography and administered activity in (mBq) derived from each examination and procedure is recorded. The mean summarizes all the data; it is calculated by adding all the values and dividing the sum by the number of observations.

Step 2

The DRLs is approximately the level of 75^{th} percentile (3^{rd} quartile) of the average of dose distribution as applied on radiological procedures. The 75^{th}percentile (3rd quartile) is chosen as the appropriate investigation level on the grounds that if 75% of the units can operate satisfactorily below this dose level, the remaining 25% should be made aware of their potentially less than optimal performance. They should then be encouraged to work on their radiographic technique to bring their dose in line with the majority (European Commission, 1999).

Step 3

Comparison of the established DRL values obtained with the data from other countries where DRLs have been established.

THE NEED FOR DIAGNOSTIC REFERENCE LEVELS (DRLS)

Increasing concerns over radiation doses received by patients and the associated radiation risks have become a major issue in recent years [9]. Reducing radiation dose in radiological examination is of utmost importance particularly in the light of continued increase in the number of new modalities and examinations performed annually [10]. In spite of the large number of radiological examinations carried out yearly, the dose information available is grossly inadequate. In addition, there are no evidence of published data indicating the establishment of diagnostic reference levels for common radiographic examination in Nigeria [11].

The need for optimization of patient protection through implementation of measures to keep doses to patients undergoing radiology examination within acceptable ranges for the clinical purpose of each examination has been a topic of global recognition [12].

Surveys of dose estimates from different imaging modalities highlight the substantial variations in dose between some healthcare facilities for same examination or procedure and similar patient group (adults or children of defined sizes). Such observations indicate the need for standardization of dose and reduction in variation in dose without compromising the clinical purpose of each examination or procedure. Examination-specific or procedure-specific DRLs for various patient groups can provide the stimulus for monitoring practice to promote improvements in patient protection [14].

Diagnostic Reference Levels DRLs can be used to set updated values for new technologies that may allow lower dose levels to be achieved [14]. Diagnostic Reference Levels (DRLs), which is the recommended tool in achieving optimization of doses, is yet to be set or unavailable for radiology examinations and procedures in many countries especially those with low resource setting [13]. Practices are presently referenced to United Kingdom radiological practice standards, European commission and Australian Radiation Protection and Nuclear Safety Agency. More so, IPEM (2004) recommends that every country and or facility should have or set its DRLs, because practices and advancement in technology varies from one country to another and hence one country's DRL cannot be a good representation of another. It is therefore imperative to establish National, regional and local DRLs because it forms comprehensive, concise and powerful tool for optimizing radiation received by patients.

TRENDS IN DRLS

Diagnostic reference levels (DRLs) are benchmarks for radiation protection and optimization of patient imaging procedures. The use of DRLs has been shown to reduce the overall dose and the range of doses observed in clinical practice [10]. The concepts of DRLs as an investigation tool to identify situations where patient dose are high and in most urgent need of reduction has been highlighted by international commission on radiological protection in ICRP Publication 60 and 73 by the European Directive 97/43/ Euratom [29]. The numerical value of the diagnostic reference level should be tied to defined clinical and technical requirements for the medical imaging task. A selected numerical value for one situation may not be applicable to different clinical and technical requirements, even if the same area of the body is being imaged. The requirements can be general or specific.

The relative tissue dose distribution in the body should not change appreciably among patients undergoing the selected medical imaging task. A proportional change in the measured quantity should correspond to a proportional and uniform percentage change in the individual tissue doses. If the relative tissue-dose distribution in the body is appreciably different from that used to establish the DRLs, due to a different field size, field location, beam quality or other technical factor that alters the internal dose distribution, then interpretation of a change in the measured quantity with regard to the change in tissue doses would be ambiguous. The technical factors required for an examination or procedure and the resulting dose are dependent on patient size and each healthcare facility should establish specific protocols for each patient group as part of optimized practice. Protocols for pediatrics examinations can be developed for patients grouped by ranges of weight or cross-sectional area, reflecting necessary changes in optimized technique [14].

In setting diagnostic reference levels, regional, local authorized bodies and professional groups should be taking into consideration.

LIMITATIONS OF DRLS

There has been a number of approach to dose reference level used for medical imaging and they are some limitations. From global perspectives and from encounters and experience from various countries, DRLs have made significant impact in achieving dose optimization in diagnostic radiology practice. However, some problems with the way DRLs has been used was highlighted by Rehani, 2015; such as using DRLs as dose limits that should not be exceeded under normal circumstances, which becomes detrimental to patients with higher body builds who may need doses higher than DRLs to achieve adequate image quality. Diagnostic reference levels have over the years been established based on representative sample or standard sized patients or phantoms. The question that may arise is how do i categorize standard size patients in different population and race? Most patients are actually non- standard but an easier method to achieve this is to establish DRLs for different body builds taking into cognizance the weight and body mass index. Establishing DRLs is largely dependent on the type of machine, regular quality control and quality assurance, use of calibrated equipment traceable to primary standard dosimetry laboratory.

Many countries use DRLs that has been developed by other countries. It is therefore difficult to come up with newer methods and protocols because of frequent equipment's breakdown. It is therefore expedient to come up with facility or departmental policies for archiving dose data base most especially in low resource settings. Whereas DRLs mostly captures retrospective data optimization always employs prospective scientific findings, it is therefore suggested that DRLs should be prospectively carried out to actually determine how optimization steps could be achieved form most current practice. Comparative study of retrospective data and prospective data can be done to determine the differences, gap created, and the way forward. Rehani,2015 suggested the useful role played by DRL in the process of optimization however newer approaches are needed to support optimization of patient protection to remove lacunae listed above. The quantity should not be dependent upon a standard-sized patient but relates to the patient at hand, and should provide the dose value needed for diagnostic quality that the technology being used can prospectively provide for an individual patient [9].

SUGGESTIONS AND THE WAY FORWARD

Looking at the challenges of DRLs most countries with low resource settings have no DRLs and references are still being made to international established standards. It is important that every country, facility and region establish its own DRLs and this can be achieved by collaboration with radiographers across the country, the regulatory bodies and professional bodies. The major step begins when each facility begins to set its own local, regional and then national The established DRLs should be reviewed periodically and at intervals that represents a compromise between the necessary stability and the long-term changes in the observed dose distributions and be specific to a country and or region. Our equipment should be designed in such a way that it will have an in-built dose notification systems and dose index registry that will allow each facility to document dose received by patients for each imaging modality. While DRLs has no answer for larger body build and non-standard sized patients which most patient population fall within, it is therefore expedient to come up with scientific methodology that will translate and transpose into practical applications. The concept of AQD considers and incorporates the facility prior to national levels and promotes facility based actions, it also takes into consideration dose, images of acceptable quality (which is the primary reason

for imaging rather than dose which is the secondary parameter) and patient's body build. It is crucial for pilot studies to begin on AQD in all imaging modalities.

CONCLUSION

Diagnostic Reference Levels has been established in most developing countries however, the future outlook provides opportunity for advancement most especially due to the limitations noted from various empirical and systematic research highlighted in literatures. A way forward in addressing the limitations is to consider the concept of Acceptable Quality Dose (AQD) which addressed the limitations of DRLs and take into cognizance the three major limitation namely dose to body build, representative patient and image quality.

Conflict of interest

The authors declare that they have no conflict of interest

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