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ORIGINAL

Establishment of reference levels in dental diagnostics

Establecimiento de niveles de referencia en el diagnóstico odontológico

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ABSTRACT

The initial process for establishing Diagnostic Reference Levels (DRLs) should focus on several key aspects: promoting a culture of safety, training personnel, assigning clear responsibilities, implementing tools and methods for dose assessment, and ensuring adequate regulation and funding by the competent regulatory authority. Although the risk associated with dental radiological examinations is relatively low compared to natural risks, any additional risk, however minimal, is unacceptable if it does not benefit the patient. According to the International Commission on Radiological Protection (ICRP), dose limits and dose constraints are not recommended for individual patients, as they could compromise diagnostic efficacy, causing more harm than benefit. Therefore, it is crucial that dental radiology services implement radiological protection measures by establishing DRLs, in order to maximize the diagnostic benefits while minimizing the risk to the patient. A methodology for establishing DRLs in dental clinical practice is proposed, including justification of appropriate radiological examination, optimization of radiological protection, and correct use of DRL values.

Keywords: Diagnostic Reference Levels; Radiological Protection; Dental Radiology; Dose Optimization; Patient Safety.

RESUMEN

El proceso inicial para establecer los Niveles de Referencia para Diagnóstico (DRLs) debe centrarse en varios aspectos fundamentales: la promoción de una cultura de seguridad, la capacitación del personal, la asignación de responsabilidades claras, la implementación de herramientas y métodos para la evaluación de las dosis, y la garantía de una regulación adecuada y financiamiento por parte de la autoridad reguladora competente. Aunque el riesgo asociado con los exámenes radiológicos dentales es relativamente bajo en comparación con los riesgos naturales, cualquier riesgo adicional, por mínimo que sea, resulta inaceptable si no beneficia al paciente. Según la Comisión Internacional de Protección Radiológica (ICRP), no se recomiendan límites de dosis ni restricciones de dosis para pacientes individuales, ya que podrían comprometer la eficacia del diagnóstico, causando más daño que beneficio. Por lo tanto, es crucial que los servicios de radiología dental implementen medidas de protección radiológica mediante el establecimiento de DRLs, con el fin de maximizar los beneficios del diagnóstico mientras se minimiza el riesgo para el paciente. Se propone una metodología para establecer DRLs en la práctica clínica dental, que incluye la justificación del examen radiológico apropiado, la optimización de la protección radiológica y el uso correcto de los valores de DRLs.

Palabras clave: Niveles de Referencia para Diagnóstico; Protección Radiológica; Radiología Dental; Optimización de Dosis; Seguridad del Paciente.

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INTRODUCTION

Dental X-rays play a fundamental role in diagnosing oral diseases and planning and monitoring dental treatments. According to the World Health Organization, more than 80% of the artificial radiation exposure received by the population comes from diagnostic practices. In addition, the United Nations Scientific Committee on the Effects of Ionizing Radiation has identified dental radiography as one of the most common radiological procedures.[1]

Although the radiation dose associated with a dental radiographic examination is relatively low compared to other radiographic techniques, such as digital radiography or computed tomography and is usually less than the natural background radiation exposure during a typical day, any additional risk is unacceptable if there is no clear benefit to the patient. Therefore, dental radiology services are strongly recommended to implement radiation protection measures to maximize clinical benefits with the lowest possible risk. To a large extent, radiation-related pathologies could be reduced with appropriate preventive and protective intervention, as suggested by several recent studies.[2,3,4]

The initial process for establishing Diagnostic Reference Levels (DRLs) should focus on several fundamental aspects: promoting a culture of safety, training staff, assigning clear responsibilities, implementing tools and methods for dose assessment, and ensuring adequate regulation and funding by the competent regulatory authority. Furthermore, in all diagnostic medical practices, a process of procedural justification is carried out in which professional associations collaborate closely with the competent authorities. Even when a procedure is established as a standard, each case must be justified by the requesting physician and the specialists responsible for performing it.

According to the International Commission on Radiological Protection (ICRP), it is not recommended to establish dose limits or restrictions for individual patients, as these may compromise the effectiveness of the diagnosis, causing more harm than benefit. Therefore, the primary focus should be justifying radiological examinations, optimizing radiation protection, and correctly applying DRLs.[5] In this context, a methodology for establishing DRLs in dental clinical practice is presented, which is based on the justification of the appropriate radiological examination, the optimization of radiation protection, and the correct use of DRL values.

Selection of the appropriate radiological examination: Justification of the examination

The justification of a diagnostic practice is based on the premise that the information obtained will contribute to confirming a diagnosis or guiding a therapeutic strategy. For a radiological procedure to be justified, the expected benefit must outweigh that provided by an alternative technique involving lower radiation doses or no exposure to ionizing radiation.[6] It is important to note that the benefits of radiological procedures usually outweigh the risks when performed within the standards of good practice.[7] When assessing the justification for a radiological examination, previous radiographs in the same region to be investigated should be considered unless they are part of the follow-up of an ongoing treatment. The final decision to justify a radiological examination is at the specialist's discretion.

Regarding justification in dental radiography, it is recommended:[8,9] "For the justification process to be carried out correctly, the selection of dental radiographs must be based on each patient's medical history and a clinical examination." The routine use of radiographs for diagnosis based on a generalized approach rather than individual prescriptions is unacceptable. A routine (or screening) examination is one in which a radiograph is taken regardless of the presence or absence of clinical signs and symptoms.

In addition, in radiology, guidelines help in the process of selecting the appropriate image. Such guidelines, called "selection criteria" or "referral criteria," exist for both medical and dental images.[8] Referral criteria have been defined as:[9,10] descriptions of clinical conditions derived from the patient's signs, symptoms, and history that identify patients likely to benefit from a particular radiographic technique. When referring a patient, it must be ensured that adequate clinical information and sufficient patient history are provided to the person responsible for the exposure. A request to perform, for example, a CBCT (cone beam computed tomography) would not be considered adequate clinical information.[8]

The general justification criteria can be summarized as follows:[9]

- Ensure that X-ray images are not selected unless a clinical history and examination have been performed.
- Select X-rays for each patient based on their clinical needs, not "routine" practices.
- Always consider the consequences of radiation doses when selecting X-rays.
- Consult available professional guidelines to assist in the selection of X-ray examinations.
- Consider pediatric patients' different imaging needs and radiation risks when selecting radiological examinations.
- Use CBCT when appropriate, not just because the equipment is available.

Diagnostic reference levels in the protection context: optimization of radiation protection

The concept of DRLs was introduced by the ICRP[11] and included in the EURATOM Directive 97/43, with the preparation of a specific document on the subject in 2001 by ICRP Committee 3. This is a concept with a specific application in the field of medical exposure, referring to dose levels in radiodiagnostics determined based on measurements and/or calculations (or levels of activity administered in nuclear medicine) corresponding to routine examinations performed on patients with "standard" characteristics in a given country or region.

DRLs are indicators of equipment quality and procedures; they do not apply to individual cases, do not constitute limits, and are not "optimal doses." Their numerical value does not arise from an average value. However, it is established using a statistical method considering the 75th percentile of the distribution of measured doses (or administered activities). This means that in 25% of cases, the doses (or activities) are above the DRLs.[12] Thus, the dynamic feature of DRLs is to start from the knowledge of local

reality and try to modify it by progressively reducing doses until an "optimal" value is reached.

DRLs are used in clinical radiodiagnostics to determine whether the radiation dose levels applied to a patient during a specific procedure under routine conditions are exceptionally high or low while ensuring that image quality is not compromised.[11] It is important to note that DRLs do not apply to specific individuals but represent reference values for population groups.

Numerous studies have confirmed the effectiveness of DRLs as a tool for optimizing radiation protection in diagnostic and interventional medical procedures, ensuring adequate patient exposure.[13,14] However, their implementation in some Latin American countries, such as Venezuela and Chile, has been hampered by outdated legislation regulating the safe use of ionizing radiation in medical practice.[4,15] In Colombia, its application is relatively recent, requiring obtaining a license to use ionizing radiation-generating equipment in dental radiography services.[16]

Here in Brazil, the outlook is more uncertain. Following the publication of Resolution RDC No. 330 of December 20, 2019, the DRLs in dental radiology that previously existed in Ordinance 453/98 were eliminated: periapical radiography of adults and panoramic radiography.[17] Resolution 330 was revoked in April 2022 when Resolution RDC No. 611 of March 9, 2022, came into force, which also does not include DRLs for dental radiology.[18] However, Regulatory Instruction IN No. 94 of May 27, 2021[19] establishes the health requirements for quality control and safety in extraoral dental radiology systems, as well as the minimum acceptance and quality control tests that must be performed by health services, determining the respective frequencies, tolerances, and restriction levels, presenting in Annex II the representative dose values in radiodiagnostics for a typical adult patient, that is, the same values as the DRLs previously established in Ordinance 453/98.[20]

A DRL is defined as a readily measurable quantity that allows the amount of radiation used to perform a specific clinical task to be evaluated.[21] The ICRP recommends the following quantities for use as DRLs in dental radiology: in intraoral radiography equipment, the dosimetric quantity is the incident air kerma ($K_{a,i}$), and in panoramic radiography equipment, the dosimetric quantity is the area air kerma product ($P_{K,A}$). On the other hand, the "typical DRL value" in dental practice refers to the DRL of a dental facility with one or more X-ray rooms. In this case, the DRL is calculated using the median of the selected quantity, which tends to be more typical of the dose for a standard patient, as it is less affected by high individual outliers than the mean. The DRL for dental centers in a town or city is called the "local DRL value"; for multiple facilities across a country, it is called the "national DRL value"; and for multiple countries in the same region of the world, it is called the "regional DRL value," using the median value of the available national values.

DRLs are established for different types of equipment and procedures, grouping patients according to their age and, primarily, their weight. However, in dental radiology, especially in intraoral and panoramic radiography modalities, exposure parameters are relatively independent of patient size. Intraoral radiography equipment typically has a fixed voltage (kV) and current intensity (mA) with an adjustable timer. Therefore, the measurement of the output at the cone tip with the appropriate settings can be considered as the $K_{a,I}$ (or the patient dose per unit), while the $P_{K,A}$ measured at the tube outlet of panoramic radiography equipment represents the typical value for each piece of equipment. These values are determined during equipment quality control.[16]

Establishment of DRLs in dental clinical practice: fundamental considerations

Regulation

To ensure proper practice in dental radiology, it is essential to have regulatory requirements that establish DRL values, as well as their application and the optimization of protection in dental medical exposures. Given that patient dose management varies from country to country,[22] creativity will be required when establishing DRLs and implementing an optimization program. It is essential to adapt these measures to the particularities of each national context to ensure safe and effective radiological practice in dental care.

Selection of the dosimetric quantity

The dosimetric quantity selected should be directly related to the modality studied. Table 1 shows the dosimetric quantities for establishing DRLs in dental radiology, as recommended by the ICRP.[23]

DRL values

DLRs can be established by distributing the medians of the dosimetric magnitudes measured in a sample of individual patients or teams (intraoral and panoramic radiography) in different geographical areas. The median is considered a more robust estimator (statistic) than the mean and, with a more significant number of patient dose data, is considered to provide a more representative measure of the patient population. For areas covering between 10 and 20 services, the local DRL will be established as the third quartile of the distribution of the medians. In the case of fewer X-ray rooms or a single facility, a "typical value" can be defined as the median of the distribution of the measured doses and used similarly. To establish national DRLs, a large sample of healthcare facilities and dental procedures involving ionizing radiation in that country is required. Regional DRLs, which are already defined, apply to groups of countries that employ similar practices.[23]

Table 1. Dosimetric magnitudes suitable for establishing DRLs in dental radiology

Type	Recommended size	Recommended unit
Intraoral radiography	$K_{a,i}$	mGy
Panoramic radiography	P_{KA}	$mGy.cm^2$
	DLP	mGy.cm

Lateral skull radiography	$K_{a,e}$	mGy
	P_{KA}	mGy.cm^2
Cone beam computed tomography, CBCT	$K_{a,r}$	mGy
	$CTDI_{vol}$	mGy
	DLP	mGy.cm
	P_{KA}	mGy.cm^2

Source: Adapted from ICRP[23]. $K_{a,i}$: Kerma in incident air; P_{KA}: Air kerma product; DLP: Dose length product; $K_{a,e}$: Kerma in air at the entrance surface; $K_{a,r}$: Kerma in air at the reference point at the patient entrance; $CTDI_{vol}$: Computed Tomography Dose Index (volume).

Facilities

To establish DRLs, it is crucial to define the geographical area where they will be evaluated and applied. A DRL can be derived from 10 to 20 X-ray rooms or health centers in a local setting. However, conducting a comprehensive survey would be a complicated task in large countries with hundreds of health facilities. Instead, randomly selecting a small proportion of these facilities may be a good starting point. Results from 20 to 30 services may be adequate initially, provided that a sufficient number of patients (≥ 20) are included. In smaller countries with fewer than 50 services, an initial sample covering 30 to 50% of these facilities may be sufficient. As the infrastructure for data collection improves, consideration may be given to expanding the number of facilities included in subsequent studies to achieve more representative coverage.[23]

Once DRLs have been established, optimization studies may be considered at three-year intervals, except for CBCT, which should be done annually. This will depend on the conditions in each country or region, considering the variability of study results, the introduction of new technologies or image processing software, and the availability of personnel and resources to conduct these studies.[5]

Patients or phantoms

Most procedures base their strategy on measurements taken on individual patients and classified by age, weight, or both. However, there are some limited circumstances in which the performance of the equipment can be evaluated under standard conditions to estimate the correct dosimetric magnitude, as may be the case with intraoral radiography. Table 2 describes the proposed evaluation methods for establishing RMLs in dental radiology.[23]

Data collection methods

Manual collection remains an option, especially in prospective studies. When the number of facilities is small, printed forms adapted to the examination may be used in combination with the methods described in the previous section. However, adopting automatic exposure control systems in the context of DRLs offers the advantage of retrospective review of patient examination information. Data collection from the radiological information system (RIS) allows for including many patients.

Table 2. Proposed evaluation methods for establishing DRLs in dental radiology

Type	Evaluation Methods
Intraoral radiography	Measurement of equipment performance in standard configuration.
Panoramic radiography	Measurement of PK,A or DLP in standard configuration.
Lateral skull radiography	Patient evaluation.
Cone beam computed tomography, CBCT	Patient evaluation.

Source: Adapted from ICRP,[23] PKA: Kerma product in air-area; DLP: Dose product-length.

The DICOM (Digital Imaging and Communication in Medicine) standard has developed a specific format for this purpose, known as the Structured Radiation Dose Report (SRDR), designed for recording and storing information on radiation doses in various imaging modalities.[24] The patient dose management system allows information collected from the RDSRs to notify clinical staff and medical physicists when dosimetric magnitudes exceed certain pre-established levels, especially in the case of high skin doses, which generates an alert for clinical follow-up of possible radiation injuries. However, it is necessary to configure the sending of RDSR files from the modalities to the RIS/PACS and use specific software that can manage this information, including verifying the transmitted data.[25]

Finally, automatic dose management would provide quick access to the patient's age and weight, the doses received by patients, and the technical parameters of the equipment, as well as the export of a set of filtered data for further analysis. The most extensive system worldwide is the ACR-CT Dose Index Registry of the American College of Radiology (ACR), with over 800 facilities and 16 million exams.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

AUTHORSHIP CONTRIBUTION

Conceptualization: Manuel Villarreal University.
Research: U. Manuel Villarreal.
Methodology: U. Manuel Villarreal.
Writing - original draft: U. Manuel Villarreal.
Writing - revision and editing: U. Manuel Villarreal.

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