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OPTIMIZATION OF RADIATION PROTECTION OF CHILDREN DURING X-RAY EXAMINATION — EXISTING NATIONAL AND INTERNATIONAL APPROACHES

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ABSTRACT. The use of modern imaging modalities based on sources of ionizing radiation, is an essential part of system of medical care in pediatric practice. Fixed increase in availability and amount of X-ray imaging (radiography, computed tomography, interventional examinations, etc.) leads to corresponding increase in patient doses. To ensure the radiation safety of the population of the Russian Federation from medical sources of ionizing radiation, an integrated approach is applied using the basic principles of radiation safety — justification and optimization. One of the fundamental principles of radiation safety is the principle of optimization, which is reflected in all national legislative documents. Unfortunately, modern approaches to optimization of radiation protection of children are not sufficiently covered in these documents. The analysis of existing national and international regulatory documents has indicated significant differences in the implementation of optimization of radiation protection of children from X-ray examinations. In international practice, the optimization principle is widely used, based on the concept of diagnostic reference levels and quality assurance programs for X-ray examinations. The national legislative documents have been harmonized with the international documents (considering diagnostic reference levels, quality assurance programs, control of patient doses, etc.). However, they are hindered by incomplete development of practical methodology and lack of information about the specifics of radiation protection of children. In addition, current guidelines that define the quality assurance program do not cover all methods of X-ray examinations and do not contain any information about quality assurance programs for pediatric X-ray examinations. Therefore, the question of the need to improve the legal and regulatory framework in the field of radiation safety of children during X-ray examinations remains relevant.

KEY WORDS: X-ray diagnostics; radiation protection; radiation safety; X-ray examination; medical exposure; children.

ОПТИМИЗАЦИЯ РАДИАЦИОННОЙ ЗАЩИТЫ ДЕТЕЙ ПРИ ПРОВЕДЕНИИ РЕНТГЕНОРАДИОЛОГИЧЕСКИХ ИССЛЕДОВАНИЙ — СОВРЕМЕННЫЕ ОТЕЧЕСТВЕННЫЕ И ЗАРУБЕЖНЫЕ ПОДХОДЫ

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РЕЗЮМЕ. Применение современных методов диагностики, в том числе с использованием источников ионизирующего излучения, является неотъемлемой частью системы оказания медицинской помощи в педиатрической практике. Повышение доступности и распространенности рентгенорадиологических исследований (рентгенологические исследования, компьютерная томография, интервенционные исследования и пр.) ведет к росту доз облучения пациентов. Для обеспечения радиационной безопасности населения Российской Федерации при медицинском облучении применяется комплексный подход с использованием основных принципов радиационной безопасности — обоснования и оптимизации. Одним из основополагающих принципов радиационной безопасности является принцип оптимизации, который отражен во всех отечественных нормативно-методических документах. К сожалению, вопросы оптимизации радиационной защиты детей в этих документах освещены недостаточно. Проведенный анализ существующих отечественных и зарубежных нормативно-методических документов показал наличие различий в реализации принципа оптимизации радиационной защиты детей при медицинском облучении. В зарубежной практике широко используется принцип оптимизации, основанный на концепции референтных диагностических уровней и программах обеспечения качества проведения рентгенорадиологических исследований. Отечественная нормативно-правовая база в вопросах оптимизации радиационной защиты гармонизирована с зарубежной (РДУ, программа обеспечения качества, контроль доз и пр.). Однако к ее недостаткам можно отнести неполную проработанность практической методологии и отсутствие информации о специфике радиационной защиты детей. Кроме того, действующие методические указания, которые определяют программу обеспечения качества, охватывают не все методы рентгенорадиологических исследований и не содержат какую-либо информацию о программах обеспечения качества в случае, если рентгенорадиологические исследования выполняются педиатрическим пациентам. Именно поэтому актуальным становится вопрос о необходимости совершенствования законодательной и нормативно-правовой базы в области радиационной безопасности детей при медицинском облучении.

КЛЮЧЕВЫЕ СЛОВА: лучевая диагностика; радиационная защита; радиационная безопасность; рентгенорадиологические исследования; медицинское облучение; дети.

BACKGROUND

Nowadays, the basic principles of patient protection from medical radiation exposure are reflected in all fundamental national regulatory documents [13, 16, 21]. Unfortunately, there is no information about the peculiarities of radiation protection of children in these fundamental documents, although many problems are unique for children's radiation diagnostics compared to adults. That is why taking into account the peculiarities of children's organism is an important element for providing effective medical care to the paediatric population.

Children have a number of peculiarities that cause differences in approaches to radiation protection between adults and paediatric patients during X-ray radiological examinations [10]. For example, it is necessary to take into account anatomical and physiological features of the child's body, differences in radiosensitivity of individual organs, tissues and the body as a whole in children at different age periods. Another factor that distinguishes imaging in children from imaging in adults is the continuous changes in the imaging of various organ systems during normal childhood development. In addition, children are characterised by a rather wide range of anthropometric characteristics, even within the same age category [30].

For the successful performance of radiotherapy in paediatrics, it is important to create a favourable and comfortable atmosphere for children. If necessary, immobilisation devices can be used to allow children to undergo X-ray radiological examinations without sedation, as young children are generally unable to remain still and in a certain position for the required time. X-ray radiological examinations should also take into account that verbal contact with children is not always possible, often parents or legal representatives of the child are involved in the X-ray radiological examinations process [30].

In addition, in recent years there has been an active introduction into medical practice of new equipment and techniques that significantly expand the possibilities of radiation diagnostics, but at the same time increase the radiation dose to patients. When applying new diagnostic methods, children can receive much higher doses per examination than adults, which requires special measures for planning and performing X-ray radiological examinations in children [1, 10, 14].

In this regard, the issue of radiation safety of patients, including children, is becoming more and more relevant. The basic principles of radiation protection of patients from medical exposure, which include the principle of justification and optimisation, are reflected in all fundamental domestic regulatory documents (The Federal law "On Radiation Safety of the Population", 99/2009, Basic Sanitary Rules For Radiation Safety (BSRFRS)-99/2010), as well as in a number of guidelines and recommendations (Methodological Recommendations 2.6.1.0066-12, Methodological Guidelines 2.6.1.2944-11, Methodological Guidelines 2.6.1.1892-04, etc.). Unfortunately, these documents contain almost no information on the specifics of exposure and radiation protection measures for children. In addition, most of the presented documents need to be updated [6, 7, 9, 13, 16, 21].

AIM

The aim is to conduct a comparative analysis of existing Russian and foreign approaches to optimise radiation protection of children under medical exposure and to identify elements of radiation protection that need to be updated.

RESULTS

Radiation safety of patients of any age should be ensured for all types of medical irradiation, provided that the maximum benefit from X-ray radiological procedures is achieved and negative radiation-induced effects on the organism are minimized [3, 4, 13, 16, 30, 31]. The main tool for realizing this goal is the use of the fundamental principles of radiation safety, the main one of which is the principle of optimization [13, 16, 21, 30, 31].

The optimization principle

The aim of X-ray radiological examinations optimization is to obtain high-quality diagnostic information with the lowest achievable radiation exposure taking into account social and economic factors [3, 19, 20, 36]. Optimization of X-ray radiological examinations in children is of particular importance because the risk of radiation effects in children is higher than in adults, and children have a longer life expectancy during which these effects may manifest themselves [10, 43].

Optimization of radiation protection includes improvement of X-ray radiological equipment, compliance of technical parameters of the equipment, and quality control of performed radiation diagnostics [13, 16, 19, 20].

According to Basic Sanitary Rules For Radiation Safety 99/2010 [16], optimization of radiation protection of patients in radiotherapy diagnostics should be implemented by the following means:

- the use of appropriate equipment and techniques in which the patient receives the lowest dose necessary to obtain an image or other diagnostic information of adequate quality;
- the use of diagnostic reference dose levels (DRDLs) for individual examinations;
- measuring or calculating the dose received by patients;
- ensuring the quality of the studies.

The first step in the optimization process is the selection of appropriate equipment for radiotherapy. The use of appropriate equipment and associated software is an important component of successful X-ray radiological examinations. It is advisable to use equipment (X-ray machines, CT scanners, etc.) designed specifically for children, especially in facilities with a high paediatric patient load. Radiological equipment used for X-ray radiological examinations in children should have the widest range of settings to optimize the protection of children [3, 19, 20].

Commissioning of radiology equipment should include prospective evaluation of patient doses and image quality parameters. In addition, paragraph 3.171 of GSR Part 3 [3] requires that even after any significant maintenance or repair work has been carried out, periodic measurements of the physical parameters of the medical equipment should be carried out (a monitoring of operational parameters [16]). In international practice, many documents from international and national organizations, as well as national and regional professional bodies, have been developed that provide detailed guidance on the quality control tests that should be performed at the recommended frequency [22–25, 29, 33–35].

As most radiology equipment and medical imaging protocols are designed for adult patients, X-ray radiological examinations may need to be modified for paediatric use. One of the key practical methods of optimization is to control the technical parameters of X-ray

radiological examinations in order to achieve the lowest possible radiation dose to obtain a high-quality diagnostic image. For this purpose it is recommended to take into account anthropometric parameters of the patient [3, 30]. The radiologist should know the features of all parameters and protocols and understand which one to choose in each case. The parameters of medical imaging protocols are subject to periodic review to ensure adequate diagnostic image quality, effective low-radiation performance and minimization of patient exposure [30].

An important component of optimizing radiation protection of children is the introduction of a system of diagnostic reference levels (DRL) recommended by the International Commission on Radiological Protection as a measure to reduce radiation dose to patients. DRL are defined as the value of a selected dose value for standard X-ray radiological examinations performed on standard equipment, for standard patients or phantoms, and are set as the 75th percentile of the distribution of dose values associated with the selected X-ray radiological examinations [19, 20, 31, 38, 39, 44, 45].

All X-ray radiological examinations performed in children, whether associated with high dose or low dose, should have an DRL. To determine paediatric DRL values, in addition to the generally accepted grading by age, it is useful to set DRLs based on anthropometric characteristics, as anthropometric data of children can vary widely within even a single age period [30].

A key goal of using DRLs is to keep patient doses as low as possible to achieve high image quality and the necessary diagnostic information [19, 20, 31, 38]. The DRL serves as a means of checking whether a patient's exposure level is greater than is sufficient to provide reliable diagnostic information. Whenever DRLs are consistently exceeded, appropriate investigations to identify the causes and corrective actions to improve clinical practice should be taken immediately. In addition, DRL should be reviewed and updated regularly, in particular when equipment or examination methods change [31].

It is important to note that exceeding DRL for individual patients is not a violation of radiation protection requirements. DRL are not a standard, but are used as a reference dose value for the purposes of internal quality control of procedures [40–42]. The established DRLs make it possible to identify medical organiza-

tions or radiotherapy departments where radiation protection of patients should be optimized in the first place [37, 38].

In foreign practice, the establishment of DRL and the use of the optimization principle are an integral element of patient protection at the international [3, 4], European [26, 32] and national [28, 46, 47] levels. International [26, 47] and national data collection programs to determine patient doses and revise DRL values are regularly conducted [27, 28, 46].

In the Russian Federation, the principle of optimization is enshrined at all levels of legislation on radiation protection in medicine. In the Federal Law No. 3 “On Radiation Safety of the Population”, the optimization principle is formulated as a principle of medical radiation protection [21]. The principle of optimization is formulated as keeping individual doses and the number of exposed persons at any source of ionizing radiation at the lowest and achievable level, taking into account economic and social factors.

In BSRFRS-99/2010 [16] the principle of optimization of patient protection is formulated in the clause 4.7 as the achievement of a useful medical effect of X-ray radiological examinations, diagnostic information of high quality or therapeutic results at the lowest possible exposure levels. The clause 4.8 contains the main ways of ensuring the optimization process. In Radiation Safety Norms-99/2009 [13] the principle of optimization is formulated similarly to BSRFRS-99/2010, but additional information isn't provided.

One of the most effective ways of optimization is the use of DRL. The concept of DRL is described in detail in Methodological Recommendations 2.6.1.066-12 “Application of DRL for optimization of radiation protection of the patient in general-purpose radiological examinations” [6]. However, in practice the optimization principle is implemented formally. One of the reasons is the absence of medical physicists in the staff of radiology departments. The existing radiation safety system is mainly oriented to medical personnel. An improvement and complication of modern methods of radiation diagnostics do not allow medical staff to perform the dosimetry of patients, analysis of their exposure levels, establishment of low-dose protocols properly [2].

It is recommended to periodically review DRL, for example, every 3–5 years. The specifics of setting and using DRL in paediatric prac-

tice are not described in Methodological Recommendations 2.6.1.066-12.

It should be noted that MR 2.6.1.3387 “Radiation Protection of Children in Radiation Diagnostics” and methodological recommendations “Hygienic Requirements for Limiting Radiation Doses to Children in Radiological Investigations” [5, 10] are fully devoted to radiation protection of children.

However, despite the fact that the main emphasis is placed on children, the activities are more theoretical than practical. However, the peculiarities of radiological exposure of children and a number of methods to limit and reduce radiation exposure are specified. For example, it is recommended to focus on the justification of procedures and to exclude examinations that are not necessary, to use alternative non-ionizing imaging methods, to use modern X-ray equipment and individual means of patient protection. Protocols for X-ray radiological examinations of children should take into account the age characteristics of patients, their anthropometric characteristics, disease specifics, equipment features and requirements for personnel. The guidelines «Hygienic requirements for limiting radiation doses to children during radiological examinations» also pay attention to private methods of radiological examination of children — radiography and rentgenoscopy, as the most frequently used ones [5].

Quality assurance program

Organizational measures aimed at the improvement of radiation protection of patients, including children, are an integral part of the optimization. Such measures include a comprehensive quality assurance program that includes aspects of quality control and continuous improvement of the quality of radiotherapy diagnostics (GSR Part 3, paragraph 3.170 and 3.182) [3].

To provide radiation safety of the public, patients and staff, it is necessary to carry out quality control activities, which include the following sections: control of diagnostic and auxiliary equipment, ensuring radiation safety of patients, education and re-education of personnel involved in the process of X-ray radiological examinations [11, 12].

An important component in this process is medical equipment. For the staff of a medical facility that uses ionizing radiation sources in its

practice, special training in the use of equipment or software should be provided. There should be a full understanding of the characteristics of the equipment, terminology or software, including the associated implications for radiation protection of patients and staff [3].

Quality control of equipment includes performing maintenance, identifying worn and damaged parts, checking the operation of all protective devices and interlocks, having and maintaining reporting forms, and monitoring the technical condition of the equipment. In addition, it is necessary to carry out daily control procedures, parameter constancy tests and calibration of diagnostic and auxiliary equipment, as well as control of microclimate of premises for compliance with sanitary and epidemiological requirements and operating conditions recommended by the equipment manufacturer [3].

In medical organizations the control of radiation doses to patients is mandatory. Paragraph 3.168 of GSR Part 3 requires that patient dosimetry should be performed during X-ray radiological examinations [3]. In foreign practice, X-ray machines are equipped with clinical dosimeters and integrated into a unified PACS (Picture Archiving and Communication System) or RIS (Radiological Information System), which allows collecting and recording data automatically. Knowledge of typical doses forms the basis for the application of dose reduction methods within the framework of optimization. Image storage capabilities allow for methodical evaluation and documentation of information without creating additional images reducing the patient's dose.

Another key point is the training of medical staff in radiation protection. All procedures, especially high-dose procedures, should be performed by experienced paediatric staff because of the potential high dose to patients. Mechanisms for improving the competence of health care professionals in radiation protection include traditional education and training, such as in medical school, or specialized training for the profession, web-based or on-the-job training [3].

Professional organizations and communities play a role in ensuring radiation protection and safety in the medical use of ionizing radiation. Their functions may include setting standards for training, qualifications and competence in a given area of specialization and publishing guidance for practice. Professional organiza-

tions should play a leading role in developing principles of patients referral for investigation when justifying medical exposures for each patient. In addition, professional organizations and communities promote the dissemination of accurate information on radiation protection and safety for physicians, patients and their parents.

The main current national regulatory and methodological documents on radiation protection of patients and medical staff do not address the issues of quality assurance in radiation diagnostics. These documents address only some aspects of quality control within the framework of the program of control of technical parameters of diagnostic equipment [13, 15, 16].

Current guidelines, which define the quality assurance program, include requirements for control of diagnostic and auxiliary equipment, ensuring radiation safety of patients, as well as requirements for training and retraining of personnel involved in the process of diagnostic examinations (Methodological Guidelines 2.6.7.3651-20, Methodological Guidelines 2.6.7.3652-20) [11, 12]. But, unfortunately, they do not include all X-ray radiological examinations — only computer tomography (CT), positron emission tomography (PET) and PET/CT methods. In addition, these documents do not contain any information on quality assurance programs for X-ray radiological examinations performed on paediatric patients.

The system of monitoring and recording patient doses is an integral part of radiation protection optimization. In the Russian Federation, this system is implemented in all medical organizations within the framework of the USCID (unified system of control and accounting of individual radiation doses to citizens) and statistical reporting form No. 3 "Information on patient doses during medical X-ray radiological examinations" [17, 18]. Within the framework of this system, it is possible to obtain information on collective and average effective doses for the most common X-ray radiological examinations (radiography, fluoroscopy, computed tomography, interventional studies, etc.) at the level of a medical organization. Unfortunately, the reliability of these data is low because the doses of individual patients are not taken into account and are averaged over the entire medical organization.

Estimated dose values (effective dose) are used to estimate radiation doses to individual

patients. Measured dose values are not centrally collected. Effective doses are calculated using transition factors (from measured dose to effective dose) [8, 9]. These transition factors are developed for a limited number of X-ray radiological examinations and age categories, and only if they correspond to the study parameters for which the transition factors were calculated. In the absence of an appropriate set of study parameters or when new study methods are introduced, it is difficult to calculate the effective dose. Therefore, typical effective doses are used without taking into account the specifics of individual patients and peculiarities of the study in each particular case. As a consequence, it is reasonable to improve the methods of assessment of patient doses and radiation risks during X-ray radiological examinations.

Control of diagnostic and auxiliary equipment and the quality of operational parameters is carried out in all medical organizations. It should be noted that, as a rule, it takes place only within the framework of maintenance. A sufficient number of medical physicists in the staff of medical organizations is required to implement this process in daily practice.

CONCLUSION

Thus, in despite of the fact that the domestic regulatory and legal framework for radiation protection optimization is harmonized with foreign ones (DRL, quality assurance program, dose control, etc.), its defects include incomplete elaboration of practical methodology and lack of information on the specifics of radiation protection of children. Unfortunately, there is no information on the means and specifics of radiation protection of children in the fundamental documents, although taking into account the peculiarities of children's organism is a necessary link for providing effective medical and preventive care to the child population.

The development of measures to control and assess the effectiveness of X-ray radiological examinations in the Russian Federation is entrusted to the Federal Service for Supervision of Consumer Rights Protection and Human Welfare. However, as this is outside its competence (for example, to monitor the correctness and accuracy of measurements of operational parameters), the implementation of the optimization process should be carried out jointly with the Ministry of Health of the Russian Federation,

which is currently planned to be done within the framework of the draft of the new Federal Law on Radiation Safety of the Population. In addition, quality criteria and regular audits should be introduced into the practice of medical institutions as an element of radiation protection.

ADDITIONAL INFORMATION

Author contribution. Thereby, all authors made a substantial contribution to the conception of the study, acquisition, analysis, interpretation of data for the work, drafting and revising the article, final approval of the version to be published and agree to be accountable for all aspects of the study.

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