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ANALYSIS OF THE EXISTING NATIONAL AND INTERNATIONAL APPROACHES TO ENSURING RADIATION PROTECTION OF CHILDREN DURING X-RAY EXAMINATION

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ABSTRACT. Level of using X-ray examination in pediatric practice has increased significantly over the past decade. Awareness of availability and prevalence of highly informative examinations (computed tomography, X-ray endovascular procedures, nuclear medicine) leads to corresponding increase in patient doses. In order to successfully ensure the radiation safety of the population in Russian Federation, it is necessary to develop an integrated approach based on the fundamental principles of radiation safety. The basic principles of protecting patients from medical exposure are reflected in all national legislative documents. Unfortunately, the issues of radiation protection of children are not sufficiently lighted in these documents. The purpose of this work was to analyze the existing national and international approaches to radiation protection of children from medical exposure, to identify elements of radiation protection that need updating. Principles of justification and dose limitation were chosen for our work. The analysis of key national and international approaches showed significant differences in practice of radiation protection of children from medical exposure. In foreign practice, special attention is paid to the principle of justification through the development and application of the criteria for justification of X-ray examination. It should be noted that there is no limitation of radiation doses to practically healthy individuals during screening examination. Unfortunately, today the issues of radiation safety of children are not sufficiently covered in the Russian Federation. 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 becomes actual.

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

АНАЛИЗ СОВРЕМЕННЫХ ОТЕЧЕСТВЕННЫХ И ЗАРУБЕЖНЫХ ПОДХОДОВ К ОБЕСПЕЧЕНИЮ РАДИАЦИОННОЙ ЗАЩИТЫ ДЕТЕЙ ПРИ ПРОВЕДЕНИИ РЕНТГЕНОРАДИОЛОГИЧЕСКИХ ИССЛЕДОВАНИЙ

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РЕЗЮМЕ. За последнее десятилетие значительно увеличиваются объемы применения рентгенорадиологических исследований в педиатрической практике. Повышение доступности и распространенности высокоинформативных исследований (компьютерной томографии, рентгенэндоваскулярных процедур, процедур ядерной медицины) приводит к росту доз облучения пациентов. Для успешного обеспечения радиационной безопасности населения Российской Федерации необходим комплексный подход, основанный на использовании основополагающих принципов радиационной безопасности, — обоснования и оптимизации. Основные принципы защиты пациентов от медицинского облучения отражены во всех основополагающих отечественных нормативно-методических документах. К сожалению, вопросы радиационной защиты детей в этих документах освещены недостаточно. Целью данной работы являлся анализ существующих отечественных и зарубежных подходов к радиационной защите детей при медицинском облучении, направленный на выявление элементов радиационной защиты, нуждающихся в актуализации. Для данной работы были выбраны принципы обоснования и ограничения доз. Проведенный анализ основных отечественных и зарубежных нормативно-методических документов показал наличие значительных различий в практике радиационной защиты детей при медицинском облучении. В зарубежной практике особое внимание уделяется реализации принципа обоснования путем разработки и применения критериев обоснования назначения рентгенорадиологических исследований. Следует отметить отсутствие ограничения доз облучения практически здоровых лиц при проведении скрининговых исследований. Результаты работы указывают на необходимость актуализации законодательной и нормативно-правовой базы в области радиационной безопасности детей при проведении рентгенорадиологических исследований.

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

BACKGROUND

The health of children and adolescents in the society is a topical issue and a subject of pri-

mary importance, as it determines the future of the country, the nation's gene pool, the scientific and economic potential of the society and, along with other demographic indicators, is an

important factor in the country's social and economical development.

Analysis of the dynamics of changes in the general morbidity rate of the child population over the past 10 years indicates a steady increase in the incidence of such major classes of diseases as neoplasms (for children aged 0 to 17), diseases of the endocrine system, the urinary system, and injuries, poisoning and other consequences of external causes for children aged 15 to 17. At the same time, for the entire child population, the leading place among diseases is occupied by respiratory diseases: in 2020 this indicator was 101,956.7 and 66,681.4 per 100,000 children aged 0–14 and 15–17 years, respectively [25–29]. Against this background, there is a growing trend towards increased use of modern diagnostic methods, including methods using ionising radiation sources [15]. Moreover, along with standard radiological studies, more informative radiological methods of investigation (computed tomography, positron emission tomography, interventional studies, etc.) are widely used [15]. The use of new high-tech X-ray radiological examinations is associated with increased radiation doses (both individual and collective).

In this regard, the issue of radiation safety of patients, including children, is becoming more and more urgent. The basic principles and measures of radiation protection of patients from medical exposure are reflected in all fundamental domestic regulatory documents (Federal Law No. 3 “On Radiation Safety of the Population”, 99/2009, Basic Sanitary Rules For Radiation Safety (BSRFRS)-99/2010), as well as a number of guidelines and recommendations (Methodological Recommendations 2.6.1.0066-12, Methodological Guidelines 2.6.1.2944-11, MR 2.6.1.1892-04, etc.). But, unfortunately, these documents contain practically no information on the specifics of exposure and radiation protection measures for children. In addition, most of the presented regulatory documents need to be updated, since more than 10 years have passed since their development [10–12, 14, 16, 33].

Improvement of the regulatory framework and preparation of normative documents regulating radiation safety issues, including those related to medical activities, should be carried out taking into account the standards and recommendations of international organisations. This is stated in the main directions of imple-

mentation of the state policy in the field of nuclear and radiation safety (Presidential Decree No. 585 of 13 October 2018 “On Approval of the Fundamentals of State Policy in the Field of Nuclear and Radiation Safety of the Russian Federation for the Period until 2025 and Further Perspective”) [31].

AIM

To carry out a comparative analysis of existing domestic and foreign approaches to radiation protection of children under medical exposure aimed at identifying elements of radiation protection that need to be actualized.

RESULTS

At present, the basic principles of protecting patients from medical radiation exposure are reflected in all fundamental national regulatory documents [14, 16, 33]. But, unfortunately, there is no information on radiation protection of children in these fundamental documents, although taking into account the specific features of children's organism is a necessary link for providing effective medical and preventive care to the child population. Children's organism is unique, and each age period of a child is accompanied by certain anatomo-physiological features, which should be taken into account when prescribing and conducting X-ray radiological examinations and when organising radiation safety measures for children [13].

Medical exposures are different from other exposures to the public in that people (mainly patients) are deliberately and consciously exposed. The specificity of radiation protection in medical exposures requires different approaches from those applied to other human exposures. Nevertheless, radiation safety of patients should be ensured in all types of medical exposure, provided that the maximum benefit from X-ray radiological procedures is achieved and negative radiation-induced effects on the organism are minimised [14, 16]. The main tool for realising this goal is the use of the fundamental principles of radiation safety — an justification, optimisation, normalisation (the dose limitation) [14, 16, 33]. Within the framework of this work, a comparison of domestic and foreign approaches to the application of the principles of justification and dose limitation was carried out.

The justification principle

The principle of justification is to compare the radiation risk from medical X-ray radiological examinations with the health risk from not obtaining or incompletely obtaining diagnostic information [23, 24].

In applying the principle of justification in the case of medical exposures, a specific approach is required, involving the application of three levels (three-level approach). The first level of justification is the postulate that the appropriate use of radiation in medicine is more beneficial than harmful [23, 24].

The second level of justification is based on an assessment of whether the selected X-ray radiological examinations will improve diagnosis or treatment. This level is implemented through national health authorities through the development and implementation of treatment and diagnostic standards, as well as specialised criteria for the prescription of X-ray radiological examinations developed by national associations of radiologists in collaboration with radiation protection regulators [36, 39–43].

The medical decision support system includes national or international systems of justification criteria developed by professional organisations in cooperation with radiation protection specialists — recommendations of the European Commission; eligibility criteria developed by the American College of Radiology; ESR iGuide from the European Society of Radiology and the American College of Radiology; a set of recommendations of the Canadian Community of Radiologists [34–36].

The main objective of the developed recommendations and systems of justification criteria is that physicians should refer their patients to the most appropriate imaging procedures, not only in terms of the clinical task at hand, but also in terms of radiation safety. An important feature of these guidelines and criteria is the fact that the choice of radiotherapy techniques is made according to their proven efficacy (which based on literature data for the last few years). In addition, they contain information on radiation risk to the patient or values of typical effective doses for each radiological examination. Regular updating of these recommendations and introduction of the criteria into the electronic document management system of medical organisations helps to reduce the number of

unjustified X-ray radiological examinations and has a positive impact on the results of diagnosis and treatment, as well as on the health status of patients [34–36].

At the third level of justification, it is necessary to consider the appropriateness of application of a certain X-ray radiological examination to a particular patient, taking into account the exact task of performing the X-ray radiological examination, the clinical picture and individual characteristics of the patient. The third level of justification is implemented directly in the medical organisation in the interaction between the attending physician and the radiologist. In this case, the final decision to perform X-ray radiological examination on a particular patient is made by them, primarily on the basis of their professional experience [36, 39, 40, 42, 43].

It is particularly important to consider the principle of justification when prescribing X-ray radiological examinations to paediatric patients. Because children are at higher risk of stochastic effects, paediatric trials require particular care in the justification of X-ray radiological examinations [2]. Each study should be performed only when indicated by the physician. If it indicated and justified, unnecessary multiple scans of the same area and unnecessary duplication of images should be avoided. Alternative imaging modalities that avoid the risk of ionising radiation, such as ultrasound and magnetic resonance imaging (MRI), should always be considered [37]. In addition, the patient or their legal representative should be informed of the expected benefits, risks and limitations of the proposed X-ray radiological examination, as well as the consequences of not receiving the procedure [37].

In the legislation of RF the principle of justification occupies an important place in the system of normative and methodological documents. According to the Federal Law “On Radiation Safety of the Population” from 09.01.1996, Federal Law No. 3, the principle of justification is “prohibition of all activities on the use of ionising radiation sources, in which the benefit obtained for a person and society does not exceed the risk of possible harm caused by additional exposure to natural radiation background” [33]. The same definition is given in Sanitary Regulations and Norms 2.6.1.2523-09 “Radiation safety standards (Radiation Safety Norms-99/2009)” [14].

The general requirements that should be taken into account to justify the X-ray radiological examinations are reflected in Sanitary Regulations and Norms 2.6.1.2612-10 "Basic Sanitary Rules for Radiation Safety (BSRFRS-99/2010)" [16]. They include clinical indications for diagnostic tests, selection of the most radiation-sparing methods of research and consideration of alternative diagnostic methods. The justification of therapeutic X-ray radiological examinations takes into account that the expected efficacy of treatment is superior to the efficacy of alternative methods, and the risk of refusal of radiation therapy is known to exceed the risk from radiation exposure during its administration [16].

Similar requirements apply to the justification of X-ray radiological examinations in children: the presence of clinical indications, the choice of the most radiation-sparing method for children, mandatory consideration of alternative diagnostic methods, and the fact that the planned study should not repeat recently conducted ones (2.6.1.3387-16 "Radiation Protection of Children in Radiation Diagnostics") [13]. It is important to remember that the use of X-ray radiological examinations in children should be carefully justified from the point of view of comparing the diagnostic benefit and radiation risk of possible long-term consequences.

In practice, the principle of justification is realised through a set of various regulatory and methodological documents. Unfortunately, in the domestic practice there are no recommendations and systems of criteria for justification of X-ray radiological examinations appointments similar to foreign ones. Most of the information tools that facilitate the decision-making process of a medical worker (orders of the Ministry of Health, medical and economic standards, clinical recommendations, professional communities of doctors, etc.) do not pay due attention to the issues of radiation protection of patients and are not coordinated among themselves.

Medical and economic standards are those that are characterised only by the presence of indicators of the frequency and multiplicity of use of various types of investigation. Unfortunately, they do not contain any information about the criteria for selecting radiology diagnostic methods for a particular group of diseases [19–22].

Clinical recommendations that are developed by medical professional non-profit organisations

for individual diseases or conditions are widely used in practice [1, 17, 18, 30]. It is quite convenient to use such a resource, because clinical recommendations are publicly available and regularly updates. But, unfortunately, the issues of radiation safety are practically neglected. In the section "Diagnosis" there are no clear criteria for the applicability of various methods, including radiation methods. In addition, there is no information about radiation harm (risk) due to the use of radiation diagnostic methods. This applies to both adult patients and children. To diagnose the same condition, it is recommended to use different methods in terms of the dose received — from ultrasound and MRI, which are not sources of ionising radiation, to high-dose X-ray radiological examinations, which includes, for example, computer tomography [1, 18].

However, it should be noted that there is currently a series of guidelines issued by the Moscow City Department of Health Care "The Best Practices in Radiation and Instrumental Diagnostics". A number of these guidelines have been updated together with radiation safety specialists and supplemented with information on radiation risks during X-ray radiological examinations [5–9]. For each syndromal and nosological category a list of radiotherapy diagnostic methods is given. They are divided into three groups (main method, additional method, method not shown) depending on the ranges of effective dose values. In addition, for each range of effective dose values radiation risk categories and graphical visualisation are given. It should be noted that these guidelines apply only to adult patients. In the same series of methodological recommendations there is a publication devoted to radiation diagnostics of injuries, diseases and other pathological conditions in children [4]. However, there is no information about the values of effective doses and radiation risks associated with the use of radiotherapy diagnostic methods.

Comparison of approaches to justification of X-ray radiological examinations has shown significant differences between the Russian Federation and foreign countries in the practice of radiation protection in medicine. Foreign approaches are based on the choice of X-ray radiological examinations taking into account the diagnostic efficiency, the cost of the study, and patient exposure levels (radiation risks) in the aggregate [34–36, 39–43]. In domestic practice, the choice is based only on the diagnostic ef-

iciency [1, 17–22, 30]. Thus, in foreign practice, a multifactorial approach to justification of X-ray radiological examinations taking into account the risk-benefit analysis. Implementation of such an approach is reasonable in domestic radiology diagnostics.

In the Russian Federation, in accordance with regulatory and methodological documents, the Federal Service for Supervision of Consumer Rights Protection and Human Welfare (“Rosпотребнадзор”) is responsible for the requirements for justification of X-ray radiological examinations, dosimetry and subsequent assessment of radiation risks. However, control over the fulfilment of the justification principle is beyond its competence. In addition, regulatory documents on the interpretation of radiation risks in medicine are not mandatory, but are of a recommendatory nature and, as a consequence, are extremely limited in their application in practice [3].

Thus, the development of approaches to justification of X-ray radiological examinations similar to foreign approaches should be implemented together with the Ministry of Health of the Russian Federation, which is currently planned to be implemented within the framework of the draft of the new Federal Law on Radiation Safety of the Population. At the regional level it is advisable to develop justification criteria taking into account the hardware, technical and other capabilities of a particular constituent entity of the Russian Federation. This approach is implemented by the Moscow City Health Department [4–9].

Thus, both existing and planned clinical standards should be improved by including information on radiation risk categories and effective dose ranges for all X-ray radiological examinations used. This will help doctors not only to make a reasonable approach to the choice of diagnostic imaging methods, to take into account the diagnostic efficiency of radiotherapy diagnostic methods and the patient’s exposure level, but also to inform the patient or his/her parents about the expected radiation dose and possible health consequences.

The principle of rationing (the dose limitation)

Medical radiation exposure of patients, including children, is not rationed. In modern international recommendations, the principle of dose limitation when using ionising radiation

sources in medicine is not applied, as its use may negatively affect the quality of medical care provided to patients. Publications of the Medical Commission on Radiation Protection (MCRP) 103 [23] and 105 [24] note that medical exposure is intentional and voluntary, provided that it will directly benefit the health of the patient.

The International Atomic Energy Agency (IAEA) Safety Standards GSR part 3 [2] and Safety Standard SSG-46 [38] propose an approach that recommends the use of dose constraints for X-ray radiological examinations that are conducted for professional and legal purposes and to individuals involved in biomedical research. A dose constraint is a prospective, source-specific limit on the individual dose from a source in situations of planned exposure (other than medical exposures to patients) that serves as an upper limit on the dose predicted in the process of optimizing protection from that source. Dose limits are not dose constraints, so an exceedance of a dose limit does not constitute non-compliance, but each such exceedance should be investigated [23].

Some X-ray radiological examinations, particularly when the patients are children, are best performed with the assistance of a caregiver or patient comfort person, such as a relative. In such situations, the person providing care or comfort to the patient will be exposed to radiation, usually at a low dose. Radiation protection measures for such a person should be borne in mind and dose constraints should be applied as part of this process (p. 3.173 of GSR Part 3) [2]. In addition, parents or a caregiver should be provided with lead aprons and advised to remain out of the primary ray if it’s possible.

In addition, X-ray radiological examinations include the standard use of lead or equivalent shielding of the child’s body in close proximity to the diagnostic field. However, this is only true if the shielding is properly positioned. If not properly placed, such shielding can degrade image quality and in some cases may be inappropriate. In the Russian Federation, the fundamental documents in the field of radiation protection also state that the principle of dose limitation is inapplicable in the case of medical exposure. Thus, Sanitary Regulations and Norms 2.6.1.2523-09 “Radiation Safety Norms (NRB-99/2009)” contains information that radiation protection of patients in case of medical exposure should be based on the necessity to obtain a useful effect

from the relevant medical procedures at the lowest possible exposure levels. It does not set dose limits for patients, but applies the principles of justification for prescribing medical procedures and optimising patient protection [14]. A similar requirement is contained in BSRFRS-99/2010: "Radiation safety of persons undergoing medical X-ray radiological examinations (diagnostic, therapeutic, prophylactic, research) shall be ensured by justification of such procedures and optimisation of radiation protection. The doses received by patients during radiological procedures are not rationed" [16].

The dose limitation for medical exposures applies only to persons receiving medical X-ray radiological examinations in connection with professional activities or as part of medical and legal procedures, or participating in preventive examinations or in biomedical research, who do not derive direct health benefits from radiation related procedures. The annual effective dose due to these procedures should not exceed 1 mSv [14, 16]. In addition, NRB-99/2009 stipulates that persons other than medical personnel who assist in supporting patients (critically ill patients, children, etc.) during radiological procedures should not be exposed to a dose exceeding 5 mSv per year [14].

The principle of dose limitation in medical irradiation is reflected in all international documents [2]. Moreover, the risk groups for dose limitation and the range of these doses in domestic and foreign practice are relatively the same, with the only difference being that in foreign practice the dose ranges may change depending on the benefit/harm ratio, for example, when radiating volunteers in biomedical research.

In the Russian Federation, the dose limitation for medical exposure applies to individuals who do not receive direct health benefits from radiation-related procedures, including preventive examinations [14, 16]. But according to Federal Law No. 323, a patient is an individual who receives medical care or who has applied for medical care regardless of whether he or she has a disease and regardless of his or her condition [32]. That is, a person who undergoes a preventive examination is also a patient, but the fundamental documents in the field of radiation protection of the Russian Federation state that dose limits for patients are not established. This disagreement has not been resolved at the moment. Therefore, it is necessary to refuse to limit doses in medical exposure or to reduce the risk groups to which this limitation applies.

CONCLUSION

There is no doubt that all currently developed radiation protection means and techniques are used in medicine. The existing system of regulatory and methodological support allows to effectively provide comprehensive radiation protection from medical exposure in all types of X-ray radiological examinations. But, unfortunately, it has to be stated that at present the issues of radiation safety of children in the Russian Federation are insufficiently covered. That is why the need to improve the legislative and regulatory framework at the federal and regional levels in the field of radiation safety of children during X-ray radiological examinations becomes an urgent issue.

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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