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Review
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CHOSEN ASPECTS OF RISK MANAGEMENT OCCUPATIONAL

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Abstract

In the present chapter there are discussed the threats appearing in the diagnostic and therapeutic process with particular consideration of ionizing radiation. The implementation of medical e-records, while creating the conditions of sharing them with patients and the medical staff, reduces the decision-making risk in the process of providing hospital services.

Restructuring radiological diagnostics allows for the elimination of emission of dangerous substances and the implementation of eco-friendly procedures. The implementation of the process-based approach in servicing X-ray apparatus and controlling the dose of ionizing radiation brings about the quality, accuracy and effectiveness of the diagnosis. The process of reduction of the occupational exposure to cytostatic drugs is an essential element of total management of the public hospital.

Keywords: occupational risk, ionizing radiation, environmental protection.

Jel Classification: J24

*The first step toward change is awareness.
The second step is acceptance.*
Nathaniel Branden

INTRODUCTION

The processes of providing hospital services, due to the turbulent environment and the changes taking place in methods of diagnosis, techniques of administering medications, methods of performing operations and many other fields, undergo essential transformations. The beginning of the 21st century is the period of important organizational and functional changes of the public hospital, whose asset is the

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qualified medical staff and specialized diagnostic equipment enabling the performance of the complex hospital services.

The subject of the present chapter is to indicate some significant threats occurring in the process of the implementation of digital radiography system, aiming at the improvement of quality of diagnostic tests, the elimination of generating waste harmful for the environment and the process of reducing the exposure of the hospital staff to ionizing radiation and cytostatic drugs. Both the medical and management staff should be aware of the importance of the level of risk to be able to participate actively in the process of increasing security of work with cytostatic drugs and the care of patients undergoing chemotherapy and radiotherapy.

1. THE IMPLEMENTATION OF *LEAN MANAGEMENT-LM* IN THE MANAGEMENT OF THE X-RAY DIAGNOSTIC PROCESS

The conducted research² showed that the implementation of the system of medical imaging and sending and managing picture information (*RIS- Radiology Information System*) affects the reduction of decision-making risk in the diagnostic process (79.3% of the responses). It also allows for minimization of radiation dose, accelerates the process of examination by means of performing *post-processing*. The advanced systems - *PACS - Picture Archiving and Communication System* are possessed by 39.67% of the respondents of the surveyed public hospitals. On the other hand, the elimination of X-ray chemical processing units considerably influenced the reduction of costs of the process of providing hospital services.

PACS is, above all, a powerful tool serving the purpose of the advanced, multimodal and remote diagnostics. The implementation of a new technology accelerates a diagnostic cycle, while simultaneously improving the process of cooperation of specialist radiologists with the interdisciplinary team - the receivers of medical examination; it reduces the occupational risk.

It also enables the access to the archived imaging, while simultaneously developing the effectiveness of centralized diagnostic centers and teleradiology services in the framework of i.e. the network of public hospitals. Moreover, the determinant of the digitalization process of X-ray diagnostics is the law³ giving the grounds for the process of the flow of information (medical records) and the conditions of its provision to the participants of the diagnostic and therapeutic process.

New generation of diagnostic equipment is eco-friendly and also friendly for the participants of the process of providing hospital services. While introducing the pro-environmental policy based on the norms - ISO 14001:2005, the public hospital demonstrates the willingness to provide hospital services aiming at the provision of the quality compliant with the norm ISO 9001:2008 (Olkiewicz 2012), while simultaneous respecting the requirements of the norm PN-N-18002:2000. In the present assumptions it was presumed that the above activities are implied by:

² Author's own research: *Social and economic determinants of the decision-making risk in the process of providing hospital services 2007–2011*

³The Act of 28 April 2011 on medical information system (Journal of Laws no. 119, item. 657).

- following the legal requirements in force in the field of positive impact on the environment,
- process management of medical waste,
- reduction of energy consumption,
- ecological monitoring of suppliers and subcontractors of the diagnostic process.

The beneficiaries of the *LM* implementation process are the patients and the hospital medical staff by:

- improvement of diagnostic quality of the examination process (real-time access),
- process of protecting the patient from the excessive radiation dose,
- monitoring the environment — the process of reduction of harmful medical waste,
- economic benefits — the process of archiving and redistributing picture information *RIS/PACS* and
- legal benefits — meeting formal requirements concerning the protection of personal data⁴ of the patients and authorizing the people⁵ using the system of secure transmission and storage of information.

The determinant of digitalization of X-ray diagnostics is also the implication of the process of digitalization of the patient's medical records (Figure 1 - Based on Author's own research and the Act of Law⁶).

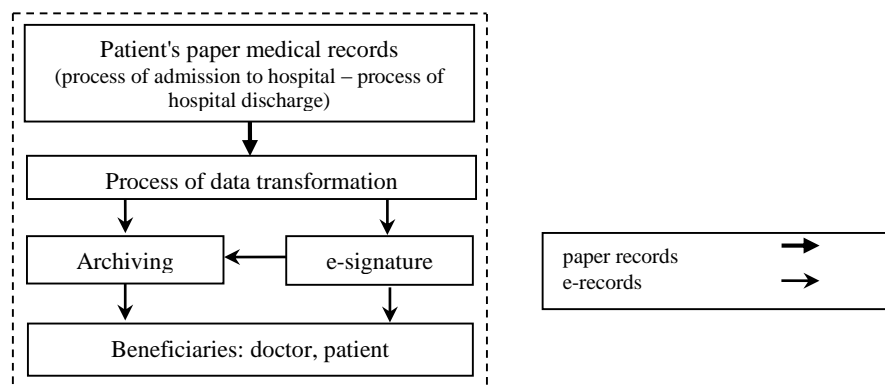


Figure 1. Model of the process of digitalization of the patient's medical records.

2. MONITORING OF THE RADIO DIAGNOSTIC PROCESS AND RADIONUCLIDE THERAPY

In the diagnostic process there are performed only the medical procedures which are allowed by the law for application. The hospital staff have expertise and power in the field of the patient's radiological protection. The dose received by patients is kept in

⁴ The Act of 29 August 1997 on personal data protection (Journal of Laws No. 133 item. 883).

⁵ The Act of 18 September 2001 on e-signature (Journal of Laws No. 130 item. 1450 as amended).

⁶ *Op. cit.*

safe ranges. The applied medical radiological equipment meets the requirements determined under the provisions and it undergoes the process of systematic control. The patient has the right for the information on the extent of exposure and the risk connected with the performed examination. The implementation of the — *TLD* (individual thermoluminescent dosimeter) method increases the security of the participants of the diagnostic process, it also allows for the total automation of measurement processes and reduction of misinterpretation. Total ranges may be exceeded only in case of significant clinical indications - the advantage resulting from the exposure exceeds the risk of adverse health effects. Dose reference ranges are understood as: "*Entrance surface dose referring to a standard-sized patient, 1.7 m tall and weighing 70 kg and are expressed as the dose absorbed at the point of intersection of the beam axis with the patient*"⁷

With reference to the medical diagnostics, it is necessary to regard as the significant ones the provisions of the Council Directive 96/29/Euratom, laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation and the Council Directives 97/43/Euratom on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure where the member states of the EU⁸ are obliged to take steps to provide and maintain the medical equipment using or generating ionizing radiation at appropriate level.

The medical radiological procedure includes the description of essential activities for conducting the examination or intervention with use of ionizing radiation to make a medical diagnosis or for examination⁹. The application of isotopic markers in the diagnostic process allows for the measurement of radiation, the attending physician receives essential information - the image of anomalies contained in the structure of the tissue under examination. Nuclear medicine, while using isotopic resources, detects significant changes in bone and soft tissues. The process of administration of radiopharmaceuticals - accumulating in tumor tissue, allows for the specification – location of undesirable tissue changes. The correct human structures are less sensitive to radiation than cancer cells coming from them, the change in relative dose value by 5% may bring about the change of the probability of cure by 25%. Radiolabels (radionuclides) allow to examine the biological processes both in a living organism *in vivo*, and after dissection of tissue or body fluids *in vitro*.

The effectiveness of a specific radiological procedure – obtaining the appropriate radionuclide is, among others, determined by:

- stream of particles – " Φ " bullets, i.e. the number of particles in 1s attributable to the surface of 1cm^2N ,
- effective cross-section " σ " for a given reaction,
- irradiation time t ,
- decay constant " λ " of the produced radioactive isotope.

⁷ Regulation of the Minister of Health of 18 February 2011 amending Regulation on the conditions for the safe use of ionizing radiation for all types of medical exposure (Journal of Laws No. 51, item. 265).

⁸ Regulation of the Minister of Health of 21 August 2006 on the specific conditions of safe operation of radiological equipment (Journal of Laws No. 180 item. 1325).

⁹ Regulation of the Minister of Health of 2 February 2007 on the detailed requirements for the form and content of the model and working radiological medical procedures (Journal of Laws No. 24 item.161).

Radionuclide activity may be calculated according to the following formula (Hrynkiewicz and Rokita 2000):

$$A = \Phi \times N \times \sigma \times (1 - e^{-\lambda t})$$

The above formula shows that long exposure (in relation to the time of life of isotope) in reactor is not profitable since while irradiating the shield for longer than about a half of half-life, basically, we do not gain the produced activity but we considerably increase the production costs.

Ionizing radiation used for diagnostic or therapeutic purposes carry some adverse health effects. The implementation of the radioisotope diagnostic and therapeutic process in the process of harmonization of the provisions in force in Poland with the guidelines of the EU consists in the introduction of the entry into the Labor Code, where both the prosumer and the hospital staff must operate so as to reduce the risk occurring in the diagnostic process.

3. OCCUPATIONAL RISK CONNECTED WITH THE EXPOSURE TO CYTOSTATIC DRUGS

The standard of cancer treatment is a complex combination therapy using two or more treatment methods enabling the achievement of the level of both the local control and the general one of the disease. The implementation of the process of the combination treatment is, among others, based on operation methods, radiotherapy and pharmacotherapy – systemic treatment. Cytostatic drugs¹⁰, which are benefit for the patients suffering from cancer, in case of the medical staff, pose a significant health risk. The risk exposure also occurs during the process of manufacturing chemotherapeutics and their use in daily practice of oncology and hematology wards (Walusiak-Skorupa, Wągrowaska-Koski, and Pałczyński 2009).

Among the biomonitoring methods there have been identified monitoring of exposure and monitoring of the effects of exposure. Biological monitoring of exposure concentrates on the measurement of concentrations of toxic substances and their metabolites in tissues, excreta and secretions of the body. Monitoring of the effects of exposure serves the purpose of the assessment of early effects of xenobiotics (Jakubowski 2004). Radiation protection of the medical staff and the patient is determined by:

- licensing and supervision of the activity connected with the exposure to ionizing radiation and
- reducing the exposure to this radiation (Figure 2- Based on: Jaracz P.: *Promieniowanie jonizujące w środowisku człowieka*, Wyd. UW, 2010, p. 36; Council of Ministers of 18 January 2005 on the ionizing radiation dose limits).

The process of reduction of negative health effects from the exposure to cytostatic drugs was based on the guidelines and recommendations of the American National Institute for Occupational Safety and Health — *NIOSH*, being a set of essential recommendations of safety at work with cytostatic drugs and other dangerous drugs in

¹⁰ In Poland the rules of conduct on the use of cytostatic drugs are regulated by Regulation of the Minister of Health of 31 August 2000

the centers of medical care.¹¹ An element rationalizing the occupational risk is also the drug policy by the implementation of *Unit*

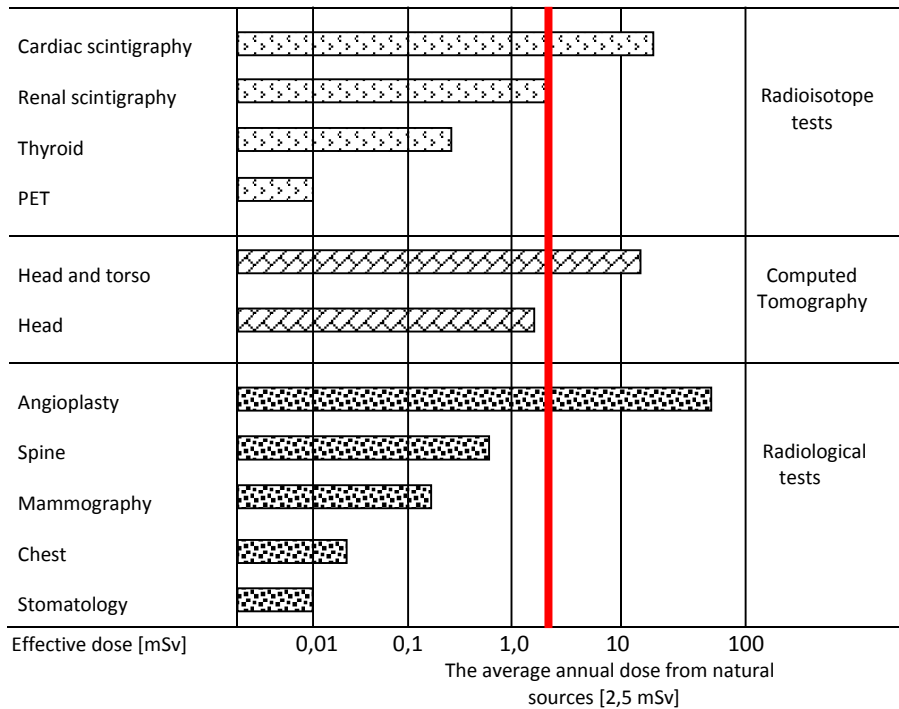


Figure 2. Average radiation dose in basic diagnostic tests

4. SAFETY MANAGEMENT OF THE DIAGNOSTIC AND THERAPEUTIC PROCESS

Radiation protection in the hospital includes the whole of the processes connected with the protection of the staff and the environment from toxicity of ionizing radiation, it is based on the principle of *ALARA* — *As Low As Reasonably Achievable*, with the consideration of essential technical, social and economic factors:

- the further the safer,
- the shorter the time of exposure the less the radiation dose,
- the shields are applied considering the fact that
- the shields against " β " radiation are made of the materials of low atomic numbers such as aluminum, plastics, glass-plastics and
- the shields against " γ " radiation are made of the materials of high atomic numbers, so that the shield is not too thick.

¹¹ NIOSH, *Alert Document Preventing Occupational Exposure to Antineoplastic and other Hazardous Drugs in Health Care Settings*, US Department of Health and Human Service, Public Occupational Safety and Health DHHS, 2004, NIOSH Publication No. 2004 p.165.

Testing the x-ray equipment and controlling the dose of ionizing radiation in the diagnostic and therapeutic process are essential determinants influencing the quality, accuracy, effectiveness — the efficiency of the diagnostic process. The development of the apparatus and diagnostic equipment minimizes the exposure of ionizing radiation dose both for the staff and the patient themselves and while reducing the decision-making risk in the diagnostic and therapeutic process it influences the increase in satisfaction of its participants.

Total quality management of the process of the provided hospital services is connected with the examination and the assessment of the process of radionuclide diagnostics and detection of irregularities - the implementation of repair and preventive actions. The essential elements in the process of technical quality control of the applied apparatus are, among others, the following reviews:

- *acceptance review* based on the norm PN-EN 61223-3-4,
- *interim review* — recommended by the manufacturer of given apparatus or radiological equipment,
- *specialist review* — correct operation of essential elements of radiological apparatus allowing for identification of sources of possible irregularities. They are made by accredited laboratories for compliance with the norm PN-EN-ISO 17025 on performing specific specialist tests.

CONCLUSIONS

The study of the literature and the author's own research confirm the thesis on the necessity of the implementation of the advance information systems in total management of occupational risk in medical enterprises. The implementation of the system of safety management in radiological diagnostics, in given conditions, aims at minimization of the dose for both the staff and the patient. Radiation protection of the medical staff is performed by means of systematic inspections of the individual dose. The implementation of the *TLD* method brought about the achievement of the European standards in this field. The dose received as a result of medical exposure is not limited since one cannot limit the patient's access to the process of treatment (increase in decision-making risk).

It is necessary to remember, though, that each use of ionizing radiation should be an activity justified by medical and economic reasons. The process of safe use of ionizing radiation in radiological diagnostics means that the benefit coming from the exposure exceeds the risk of the occurrence of adverse health effects. The implementation of interim reviews of radiological apparatus considerably improved the quality of X-ray diagnostics.

Growth in population health is a determinant. Therefore, the ideas of eco-design of hospital machinery and equipment gain an essential meaning, understood as the approach from the basis, i.e. from the moment of sourcing raw materials and finishing with the economy of worn parts — the recommendations to use the best available techniques. On the other hand, teleradiology enables the transfer of data recorded in digital form to other hospitals or reference centers, while increasing the efficiency of the cooperating units and simultaneously, developing the effectiveness of the diagnostic process and increasing the quality of the provided hospital services.

The implemented procedures, standards and instructions of the diagnostic conduct combined with technological progress considerably reduce the risk of exceeding the dose of ionizing radiation coming from medical use and having negative influence on patients.

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