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RISK MANAGEMENT AS INNOVATIVE METHOD OF MANAGEMENT IN MEDICAL INSTITUTIONS

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УПРАВЛЕНИЕ РИСКАМИ КАК ИННОВАЦИОННЫЙ МЕТОД УПРАВЛЕНИЯ В МЕДИЦИНСКИХ УЧРЕЖДЕНИЯХ

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Исследование посвящено внедрению в практику здравоохранения нового инновационного метода управления медицинскими учреждениями на основе требований международного стандарта качества ISO 9001:2015. Последняя версия стандарта требует создания в учреждениях систем менеджмента качества, опирающихся на риск-менеджмент. На примере работы городского центра первичной медико-санитарной помощи показан алгоритм выявления степени отягощенности основных и вспомогательных процессов жизнедеятельности медицинского учреждения. На основании рекомендаций стандарта ISO 9001 в деятельности учреждения выделены 31 категория рисков, сопровождающих 40 процессов и под-процессов деятельности учреждения. Показан формализованный подход к оценке значимости рисков.

Ключевые слова: риск-менеджмент, стандарт ISO 9001:2015, системы менеджмента качества, первичная медицинская помощь, медицинский аудит.

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Research is devoted to the implementation in practice of the Health Care a new innovative method of management in medical institutions on the basis of requirements international quality standard ISO 9001:2015. The latest version of the standard requires to establish in institutions of quality management systems, based on risk management. On the example of activity the city Center of primary health care is showed an algorithm for identifying the degree of loading the main and auxiliary processes in activity of the medical institution. Based on the recommendations standard ISO 9001 was allocated 31 risk category and 40 accompanying processes and sub-processes of Centre's activities. It was showed a formalized approach to assessing the significance of risks.

Key words: risk management, ISO 9001:2015, Quality management systems, primary health care, medical audit.

Introduction

Present paper is devoted to risk analysis in the practice of medical institutions with different levels and types of property that have implemented a quality management system (QMS) based on the requirements of standards series ISO 9000 and ISO 31010.

It is known that any organizations of all types and sizes face

a range of risks that may affect the achievement of their goals.

These goals may be related with a variety of activities of the organization, from the strategic programs of its activities and projects, to the tactical plans, including social, technological, commercial activities, safety measures and environmental protection, financial and economic measures, as well as social,

cultural, political and reputational impact.

If activities of the organization are associated with recurrent risk, they must be managed. **The purpose** of this paper is to analyze the risks of medical activities, depending on the basic and auxiliary processes specific to medical institutions. To **achieve this purpose** there have been studied basic and auxiliary pro-



cesses and sub-processes of QMS in Odessa's Primary Care City Center № 12 (PC Centre), as well as an analysis of potential risks for each identified processes.

The paper used the method of "Risk indices", recommended by standard ISO 31010 [1; 81].

Main part

Risk calculations for risk-based internal audit planning conducted by the modelling method described by V.P. Erdakova, T.M. Tushkina and E.E. Ermilova (2013) [2] and in accordance with the international standards ISO 31000:2009 "Risk Management" ISO Guide 73:2009. According to these standards, "risk — the effect of uncertainty on objectives" [1; Clause 1.1). Standard provides clarifications on risk assessment methods. The risk can be represented by an indicator of its potential relationship to the events, consequences or a combination of these items. Perhaps the risk expressed in the combination effects of the event (including changes in circumstances) and the likelihood of incidents related [1; Notes 3–5].

In risk management terminology, the term "opportunity" means a chance that something could happen, regardless of whether it is defined, measured or determined objectively or subjectively, qualitatively or quantitatively, and is described there with the help of general concepts or mathematical (e. g. as the probability or frequency over a given time period).

As we use the calculation model, the risk was interpreted as a result of the uncertainty. The predominant number of cases this definition is true for the negative effects of any events. Along with common to all areas of ac-

tivity types of risks, its has own specific risks in the field of health and medical care system. Their feature is connected, first of all, to the quality of diagnostic and treatment processes. Knowledge of risks, availability of system and process approaches to their assessment as well as maintenance of risk at an acceptable level is important aspects of improving the organization's QMS.

PC Centre № 12 in Odessa city is located in the central part of city, includes 125 medical staff and serves adults, as well as number students of higher educational institutions located within a radius of action the Centre. In general, the center provides medical services for 86,000 residents.

The risks analysis accompanying the PC Centre's activity was conducted taking into account internal and external contexts [1]. Establishing the context defines the basic parameters for managing risk and sets the scope and criteria for the rest of the process. Establishing the context includes considering internal and external parameters relevant to the organization as a whole, as well as the background to the particular risks being assessed.

According to the requirements standard ISO 31010, in establishing the context, the risk assessment objectives, risk criteria, and risk assessment program are determined and agreed. For a specific risk assessment, establishing the context should include the definition of the external, internal and risk management context and classification of risk criteria (see Fig. 1):

At the analysis of hospital activity it has been used the concept of process approach, rec-

ommended by ISO 9001[3]. The process providing standard of care to the urban population was considered as a closed loop, formed by four successive sub-processes (Stewart — Deming Cycle): "Plan — Do — Check — Act".

This approach has revealed the following main and auxiliary processes and sub-processes of QMS in the routine work of PC Centre № 12, as reflected in Table 1.

The 40 processes and sub-processes ($k=40$) were identified in the QMS of PC Centre and are grouped into the following groups: 1gr.: "The processes of therapeutic and diagnostic activities", 2gr.: "The processes of documentation"; 3gr.: "Resource provision processes"; 4 gr.: "Processes of compliance with ISO 9001 principles."

For example, to the main processes or business processes were attributed: design and development of diagnostic programs, the implementation of major outpatient and inpatient treatments, the performance of therapeutic, surgical and rehabilitation programs, health, innovation, and others.

To support or maintain process were attributed: personnel management, training of highly qualified personnel, analytical activity, information services, purchasing management, security agencies, and others.

To support processes were attributed and management processes: analysis of the QMS by top management, management of corrective and preventive actions, internal audit organization and others.

Transfer qualitative risk assessment processes in quantitative assessment was carried out as follows. At the first stage was formed the ma-



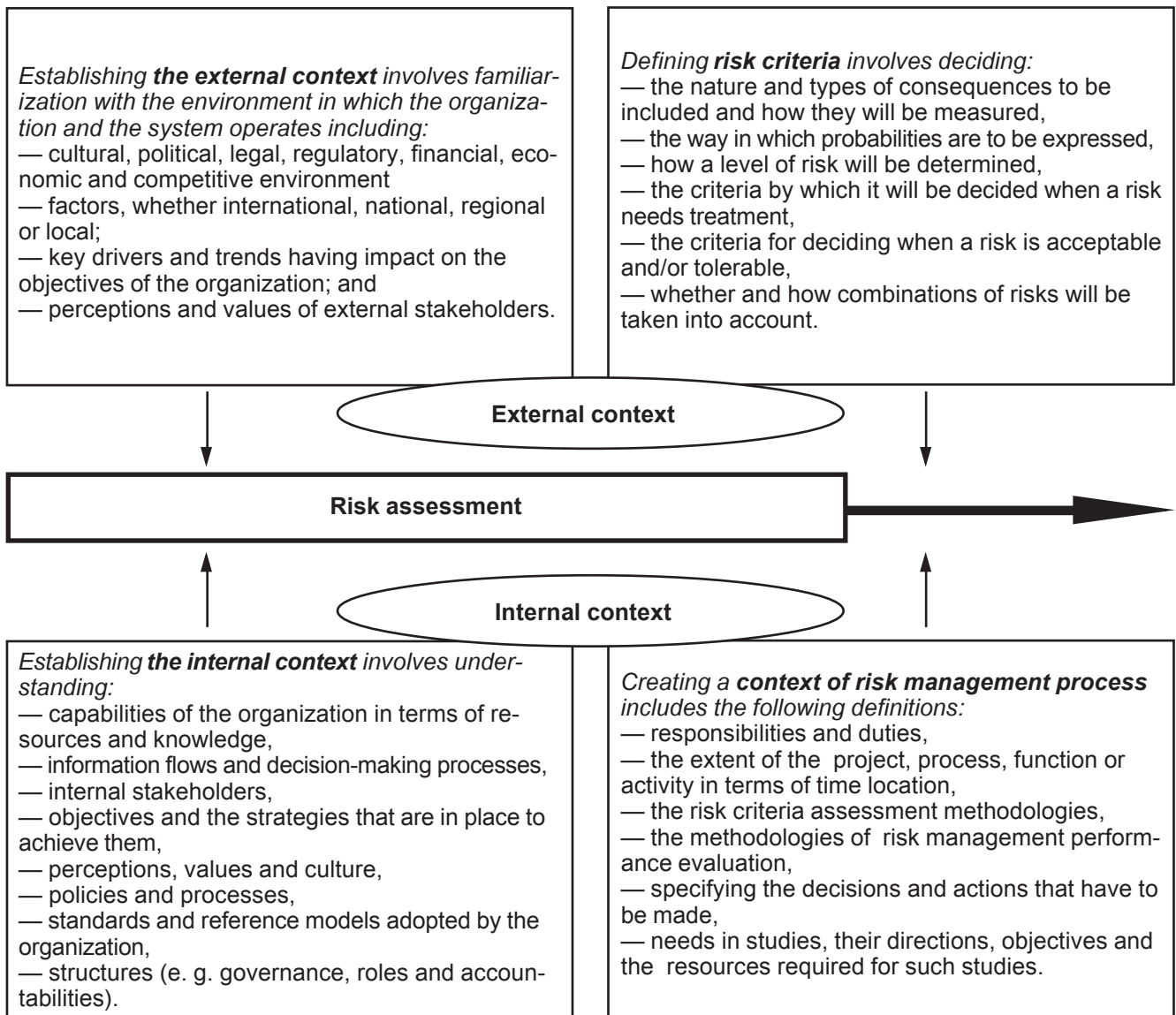


Fig. 1. The main components the risk assessment process in accordance with the requirements of ISO 31000 [1, par. 4.3.3]

trix "Processes and risks" (Table 2).

The horizontal column headers used matrix placed names of the main and auxiliary processes performed in a medical institution.

The vertical rows of headers are risk category R_i ($i = 1..m$, $m = 31$) shown in Table 3. Thus, the number of cells produced by specified table was:

$$R \times P = 31 \times 40 = 1240.$$

At the intersection of the i -rows and j -columns of matrix "Processes and risks" placed one arithmetic symbols: 0,1 (le-

vels of risk, if necessary their number can be increased) in accordance with the condition:

$$\left\{ \begin{array}{l} R_{ij} = 0 \text{ — with no risk } R_i \text{ for process } P_j; \\ R_{ij} = 1 \text{ — when there is a risk } R_i \text{ for process } P_j. \end{array} \right.$$

These values are summed in rows and columns of the matrix, the thus obtained sum divided by the sum of all matrix elements.

Thus are determined the probability of risks q_i ($i = 1..m$) and weighting factors p_j processes ($j = 1..k$).

On the basis the information available in the matrix "risks processes" may:

- to carry out a quantitative risk assessment, followed by their ranking in order of importance, in accordance with the identified problem areas of the organization and its strategic objectives;

- make a priority risk register (risk map);

- to determine the weights of all the audited QMS processes.

These weights remain unchanged for one test cycle (autumn-winter and spring-summer



The Types of Processes of QMS in the Routine Work PC Centre

Numbering processes	Types of processes	A fragment of PDCA cycle
The processes of therapeutic and diagnostic activities (PT)		
PT ₁	Receiving patients in hospital	Stage 1 (Plan)
PT ₂	Initial registration of medical records in the hospital waiting room	Stage 1 (Plan)
PT ₃	Translation of patient admissions department in the hospital	Stage 1 (Plan)
PT ₄	Organization of paraclinical examination of the patient	Stage 1 (Plan)
PT ₅	Substantiation of methods of diagnosis and treatment in a hospital	Stage 1 (Plan)
PT ₆	Palliative Care Organization	Stage 1 (Plan)
PT ₇	Clinical observation of the patient's physician	Stage 2 (Do)
PT ₈	Performing paraclinical investigations	Stage 2 (Do)
PT ₉	Perform medical appointments nurses	Stage 2 (Do)
PT ₁₀	Nutrition and care of patients	Stage 2 (Do)
PT ₁₁	Evaluation of the efficiency and effectiveness of treatment	Stage 3 (Check)
PT ₁₂	Monitoring of nurses	Stage 3 (Check)
PT ₁₃	Monitoring of nurses	Stage 3 (Check)
PT ₁₄	Monitoring of paraclinical diagnostic services	Stage 3 Check)
PT ₁₅	Monitor patients and their relatives satisfaction	Stage 3 (Check)
PT ₁₆	Analysis of the results of medical intervention in the landmark discharge summaries	Stage 4 (Act)
PT ₁₇	Carrying out a consultation and pathological conferences	Stage 4 (Act)
PT ₁₈	Doctor's reports on activities	Stage 4 (Act)
Processes of medical records (PR)		
PR ₁₉	Availability of treatment protocols and diagnostic	Stage 2 (Do)
PR ₂₀	Doctors conducting records	Stage 2 (Do)
PR ₂₁	Records keeping by nurses	Stage 2 (Do)
PR ₂₂	Consultants conducting records	Stage 2 (Do)
PR ₂₃	Keeping the accompanying medical documentation	Stage 2 (Do)
PR ₂₄	Making the discharge summary	Stage 3 (Check)
PR ₂₅	Storing medical records	Stage 4 (Act)
Resource provision processes (PP)		
PP ₂₆	Providing medicines	Stage 2 (Do)
PP ₂₇	Ensuring supply of patients and staff	Stage 2 (Do)
PP ₂₈	Information support	Stage 2 (Do)
PP ₂₉	Technical support	Stage 2 (Do)
PP ₃₀	Provide working conditions	Stage 2 (Do)
PP ₃₁	Provide positive incentive	Stage 2 (Do)
PP ₃₂	Financial security	Stage 2 (Do)
Compliance with the principles ISO 9001 (PC)		
PC ₃₃	Focus on patient	Stage 2 (Do)
PC ₃₄	Leadership in industry	Stage 1 (Plan)
PC ₃₅	The involvement of staff	Stage 2 (Do)
PC ₃₆	Systems approach	Stage 1 (Plan)
PC ₃₇	Process approach	Stage 1 (Plan)
PC ₃₈	Mutually beneficial supplier relationships	Stage 2 (Do)
PC ₃₉	Making decisions based on facts	Stage 2 (Do)
PC ₄₀	Constant perfection	Stage 2 (Do)



Matrix "Processes and Risks in the Activities of the PC Centre" [2]

R	P				q
	P ₁	P ₂	...	P _k	
R ₁	r ₁₁	r ₁₂	...	r _{1k}	q ₁
R ₂	r ₂₁	r ₂₂	...	r _{2k}	q ₂
...
R _m	r _{m1}	r _{m2}	...	r _{mk}	q _m
Weighted value of processes	r ₁	r ₂	...	r _k	,

Note. R — identified risks; P — studied QMS processes; q — the probabilities of risks

Risk Category in Audit of Quality Management System in PC Centre

No	Risk Category
The risks of a systemic nature (RS)	
RS ₁	Failure to comply the strategic goals of quality
RS ₂	Lowering the category after the establishment licensing and accreditation of health facilities
RS ₃	The closure or conversion of health institutions
RS ₄	Reducing the availability of skilled care
RS ₅	The growth of the patients and their relatives dissatisfaction quality of medical services
RS ₆	Dissatisfaction with the quality of the regional administration of treatment enshrined population
RS ₇	The high turnover of health facilities staff
RS ₈	Dissatisfaction with the quality of insurance companies of services, termination of extra-budgetary funding
The risks of a tactical nature (RT)	
RT ₉	Non-compliance with standards of diagnosis
RT ₁₀	It does not match the standards of treatment of medical technology
RT ₁₁	Inconsistency competencies of medical staff professional requirements
RT ₁₂	Mismatch state health standards of the treated patients outcomes
RT ₁₃	The lack of effectiveness of medical interventions
RT ₁₄	Lack of effectiveness of medical interventions
RT ₁₅	A shortage of qualified medical personnel
RT ₁₆	Dissatisfaction with the staff working environment conditions
RT ₁₇	The appearance, after corrective measures, repeated inconsistencies local QMS requirements
RT ₁₈	Inadequate information support diagnostic and treatment process
RT ₁₉	The use of counterfeit pharmaceutical products
RT ₂₀	Insufficient supply of resources for therapeutic and diagnostic activities
RT ₂₁	Violation of ethical standards
RT ₂₂	Failure to comply with safety regulations
RT ₂₃	Non-compliance with sanitary standards
RT ₂₄	Damage to the property of the consumer
RT ₂₅	Low activity retraining
The financial and economic risks (RF)	
RF ₂₆	Insufficient funding for health facilities
RF ₂₇	Inconsistency resources expended results achieved (the ratio of "price/quality")
RF ₂₈	Reducing the budget or off-budget financing
The risk of wrong organization auditing process (RO)	
RO ₂₉	Defect preparation the audit program
RO ₃₀	Lack of competence the audit
RO ₃₁	Failure to comply with the audit program



The weight values of risks, %

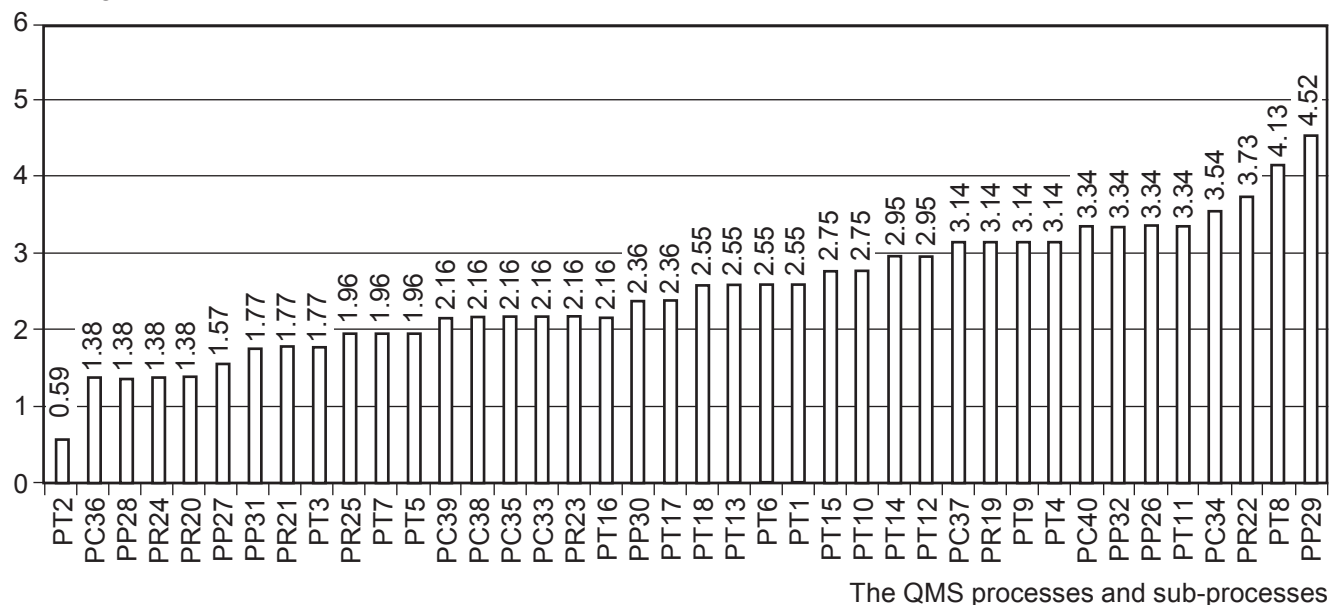


Fig. 2. The ranking by weight the audited main and auxiliary processes of QMS (burdened by risks for each of processes, in %).

seasons), with their help it made rating the quality of reference processes.

An analysis of the histograms in Figures 2 and 3, reflecting the importance of processes in the quality management system in the PC Centre, showed no sharp transition between processes with high and low risk burdened. This indicates the presence of significant amounts of intermediate processes burdened with an average risk. Detailing processes and sub-processes helps to identify additional risks and develop robust preventive measures.

Other data were obtained by analysing histograms that reflect the significance the risks in the system of quality management PC Centre. Figures 4 and 5 expressed dominance a number risks of system and tactical character. According to the ideas V. Pareto, this is group of risks which should be neutralist firstly.

The study groups have included the following risk categories:

- I gr.: RT₁₁, RS₆, PC₅, RT₁₇, RT₂₁, PC₁;
- II gr.: RT₁₂, RT₁₃, RT₁₈, RT₁₅, RT₂₀, RO₃₀;

- III gr.: RS₈, RT₁₄, RT₁₆, RF₂₇, RS₇, RT₁₀;
- IV gr.: RT₉, RT₁₉, RT₂₃, RT₂₂, RT₂₄, PC₂;
- V gr.: PC₃, PC₄, RF₂₅, RF₂₆, RO₂₈, RO₃₁, RO₂₉.

The resulting histogram is sharply unimodal. The following categories were most weighty risks:

- RT11 (Inconsistency competencies of medical staff professional requirements);
- RS6 (dissatisfaction with the quality of the regional administration of treatment enshrined population);

— PS5 (The growth of the patients and their relatives dissatisfaction quality of medical services);

— RT17 (The appearance, after corrective measures, repeated inconsistencies local QMS requirements);

— RT 21 (Violation of ethical standards) and

— PS1 (Failure to comply with the strategic goals of quality).

Conclusion

The study of materials dedicated to development strategies of national health systems in

Risk value, %

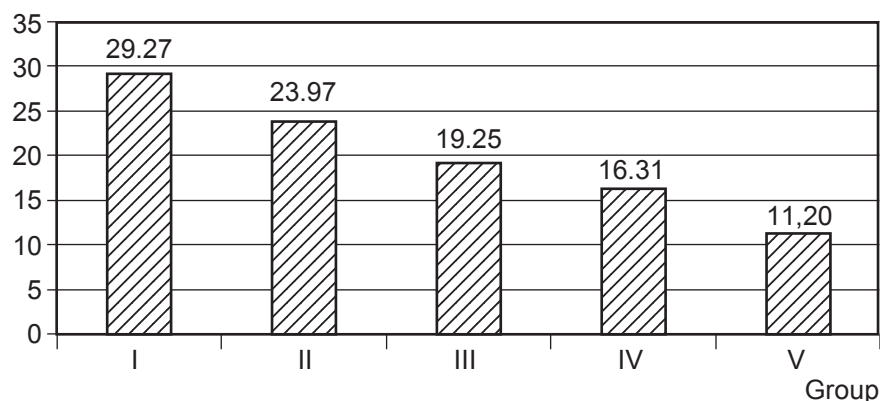
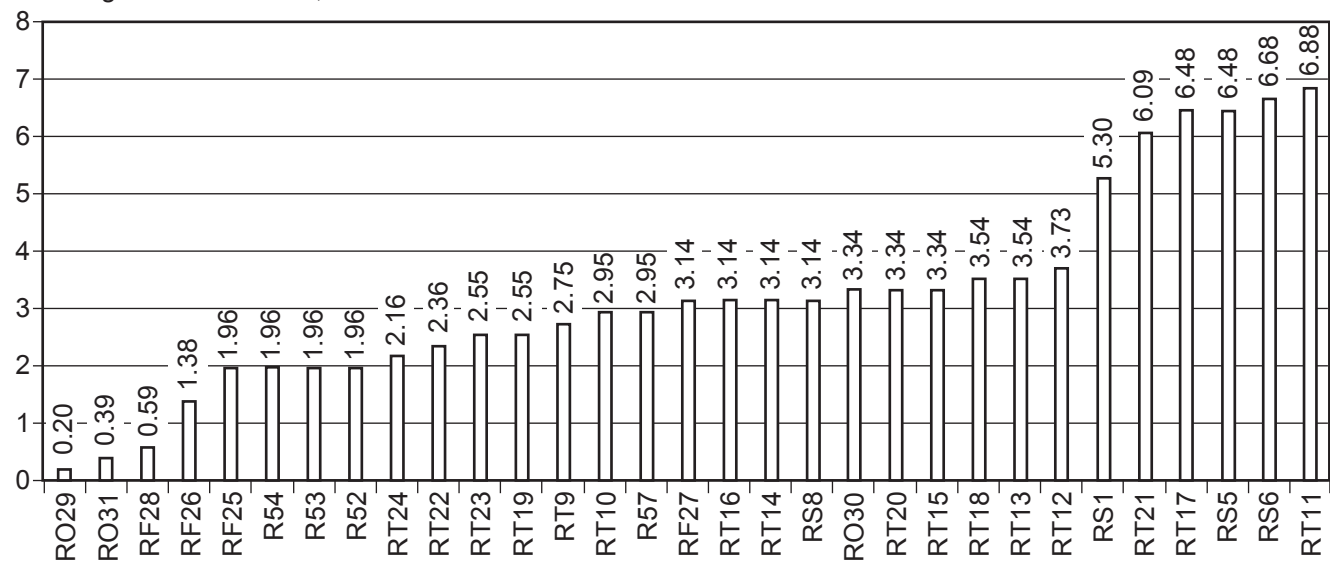


Fig. 3. The ranking the groups of processes on risks. Pareto analysis does not reveal an exponential relationship between the weight of values processes



The weight values of risks, %



The risks categories for QMS processes

Fig. 4. Ranking different risk categories QMS by weight, %

Kazakhstan [4], the Republic of Belarus [5], Estonia, Germany, Slovenia, and Poland [6], showed a common desire of governments of these countries to the creation of high-level national health systems, based on the introduction of modern systems quality management System (QMS), medical services (international quality standards TQM, ISO 9001 and ISO 9004).

As showed the analysis of function the PC Center, the activities of any organization associated with risks that must be controlled consciously. Risk management is the process of decision making under uncertainty and the possibility of future events or circumstances (intentional or unintentional) and their impact on the achievement of goals.

Risk management includes the need objectification of the risk assessment, by using some series of logical steps. Assessing risks should be carried out as they relate to diagnostic and treatment process, which they accompany.

The teamwork internal auditors should be based on commu-

nication with the persons responsible for this or that process throughout this process to improve the work of local QMS. This approach allows for a more efficient and less subjective approach to the assessment the significance particular risk. Preliminary determination of context helps organizations to identify the most significant and important factors that may be considered from the standpoint of the system or process approaches.

The risk assessment tries to answer the following fundamental questions:

— What can happen and why (for the definition of risk)?

— What are the consequences?

— What is the probability of their future occurrence?

— Are there any factors that mitigate the risk of the consequences or reduce the risk likelihood?

Without an effective integrated risk management system, the company cannot rely on the influx of investment and development stability.

As the results of risk management on the example of PC Cent-

Risk value, %

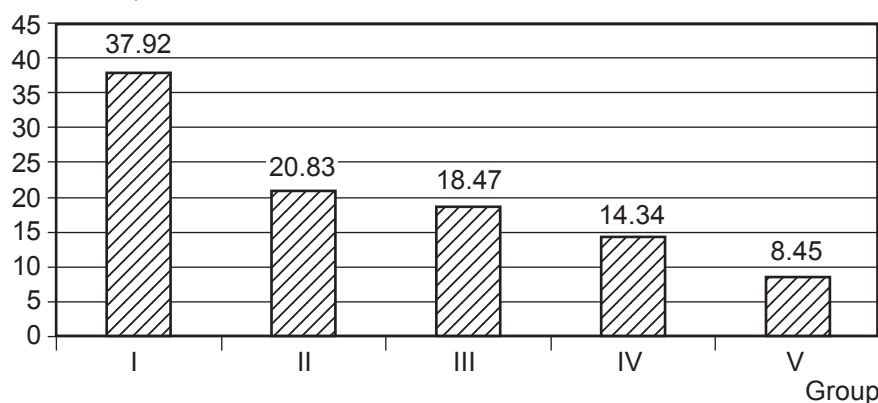


Fig. 5. Analysis of risk weight groups, using V. Pareto method makes it possible to select the first group of risks, dominant among the other risk categories



er, the most important problem is the risk of non-compliance competencies of medical staff to professional requirements. Further risk category may be derived from primary risk. Competence approach to recruiting is a new method for managers in the health care field. It was focused previously on formal compliance officer signs: nameplate data, the presence of the diploma or secondary medical education, length of service. Competence approach, combining professional knowledge and skills with communication capabilities, corporate culture and ethics is a new step on the way to achieve the highest international standards of primary health care activities.

Implementation in the health institutions management practice requirements of ISO 9001:2015 and risk management can significantly improve the performance stages reform of the National Health System in Ukraine and bring it to the level of values and demands of developed European countries.

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