

RISK MANAGEMENT AND INTERNAL AUDIT IN INTEGRATED

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Introduction

The issue of patient safety is a worldwide solved topic. World Health Organization studies have shown [25] that approximately 10 % of hospitalizations occur at patient's damage. In the Czech Republic, no study of side-effects (adverse events) has proceeded so far. Ministry of Health of the Czech Republic, however, is currently developing a series of activities to promote the Luxembourg Declaration (Luxembourg Declaration on Patient Safety), which was approved in April 2005 at the EU Member States summit and includes the following recommendations for the EU Member States:

- To allow patients a full and **free access to information** collected about them in connection with the health care provision. At the same time, to ensure the accuracy of this information and clarity for patients. To promote the principle that informed patients are better equipped to care for their health.
 - To consider the advantages of introducing a national system of **voluntary reporting of side-effects and near misses**.
 - To gradually introduce the processes of risk management in health service - for example, by creating algorithms and **quality indicators within the external quality assessment system for health service**.
 - To optimize the **use of new technologies** such as the introduction of electronic forms of medical documentation. Such documentation should include basic information on health status of patients and programs to facilitate the decision-making process (e.g. in order to minimize errors in medicine administration).
 - To establish **national forums** dealing with patient safety.
 - To monitor **safe working conditions in health service** and to make sure that the recruitment of new employees is in compliance with **principles of patient safety**.
 - To promote **intensive training for technologies users in health service** to administer their safe use.
- To include information about patient safety in the standard **training for health workers**.
 - To ensure that **national legislation** protects patient privacy as well as confidentiality of medical records and also to provide efficient access to patient information for health professionals.
 - **To create an environment where errors are used for learning**, not for blaming, humiliating and punishing "the perpetrators".
 - **To cooperate with patients** and their loved ones to inform them on the existence of side-effects in health care, including the so-called near misses.

In the frame of the Ministry of Health of the Czech Republic, there have been prepared projects on quality and safety of health services, where united methodical guidelines for selected areas to assure and improve patient quality and safety will be published. The instructions for processing effective internal rules for safe practices in health care are also under preparation. Many health facilities lack information and experience in process management. The existing internal rules do not address all problem areas and do not eliminate all known risks. Therefore the procedures implemented according to them are not effective enough. The implementation of complex integrated enterprise management systems, which includes risk management, could be a solution to the current difficult situation.

This publication should be a contribution supporting the above activities.

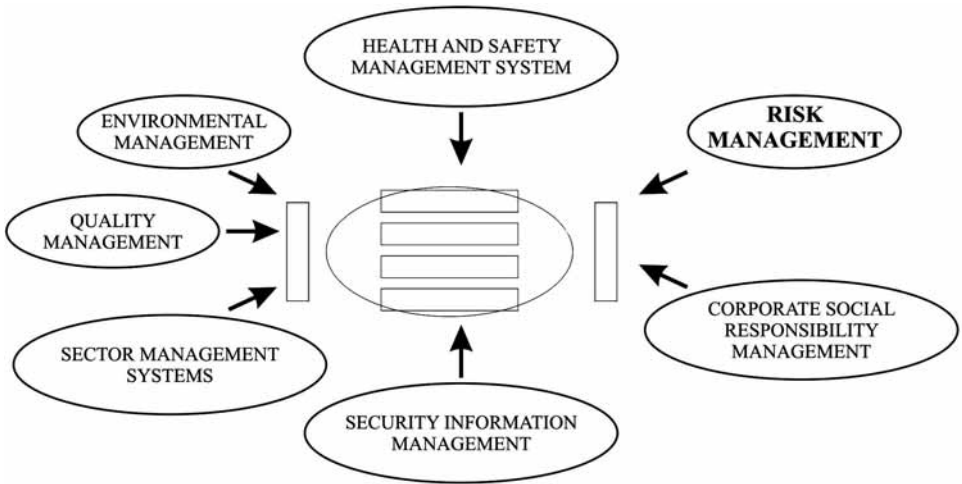
1. Integrated Management

The introduction of Quality Management System (QMS) is usually not the final stage of organizational development [15]. If an organization wants to be successful not only in terms of ownership but also from the perspective of employees, its environment, customers, etc., it must integrate together with the QMS other management sys-

tems as well. Currently, the most common integration is QMS with the Environmental Management System (EMS) and the Health and Safety Management System (HSMS) [14]. This triad is a part of the Integrated Management System (IMS) and may be subject to certification [3], [5], [6], [7]. However, neither the IMS can make the final stage of integration [11], [12]. The world trend is heading toward a single comprehensive management system [24]. A possible scheme for such integration is shown in Figure 1. [8], [9], [10,]

Trends in risk management come to the Czech Republic through foreign managers in organizations operating on the Czech market, which is confirmed by Vokounová D. in chapter “Proces zmeny” on pages 20–27 [21]. These managers bring standardized management systems, certified standards and working methods and adapt them to the environment and way of thinking in Czech conditions. Mikušová [18], [19] emphasizes the ability of risk management as part of the preparation of future crisis managers. The impor-

Fig. 1: A Comprehensive Corporate Integration of Management Systems



Source: own

2. Risk Management

The word risk has its roots in the French term ‘risque’, which means danger. Very simply, the risk can be explained as the probability of an event different from the expected event, while the most common understanding of the word always describes the event less favourable than the expected one.

The aim of corporate risk management is to identify potential events that could affect the functioning of the organization and manage risks in accordance with the adopted strategies so that the company can meet the set goals. Effective risk management in companies becomes an integral part of management processes. [4], [13], [16], [20]

tance of risk management as part of comprehensive corporate integration is also recognized by the International Organization for Standardization (ISO), which issued in 2009 the new standard ISO 31000:2009 that provides general principles and guidelines for risk management.

The standard ISO 31000:2009 can be used by any public or private organizations, because it provides general instructions only. It is not intended to promote uniformity of risk management within organizations. The proposal and implementation of risk management plans and pattern will need to take into account the various needs of a specific organization, its particular objectives, context, structure, operations, processes, products and other specific practices employed. The ISO 31000:2009 is not intended for the purpose of certification. [17]

3. Risk Management in Hospitals through Internal Audit

In the context of modern trends in integrated management (especially in manufacturing organizations) the risk management should become an integral part of "all-hospital" management. A hospital is, just as any other firm or company, a highly organized and complex system (medical technologies, medical procedures, information flows, employees, material flows). Poor quality of care for patients, the risk of accidents and work injuries and potential environmental risks arising from physical, chemical and biological risks, have basically a common cause, which is a certain degree of disorder, chaos and randomness. A well-adjusted system of the hospital should provide a certain degree of order and stability.

An internal audit in hospitals is focused mainly on (based on own experience):

- verification of the effectiveness of internal control system and recommending appropriate improvements in all aspects of health facilities;
- cooperation in identifying the risks of various activities in health facilities and proposing measures and methods to reduce their impact on the organization or the probability of their occurrence;
- verification of the completeness, relevance and accuracy of accounting, auditing financial and operating information;
- verification of the functionality and security of information systems, prevention and detection of fraud;
- verification of the economy, effectiveness and economic efficiency of all operations of the health facility;
- verification of financial management;
- verification of the performance of legal provisions, regulations and other external requirements, particularly in health care provision;
- verification of compliance with management policies designed primarily to improve patient care, its directives and other internal requirements.

An internal auditor elaborates short-and medium-term internal audit plans. Short-term plans are usually processed for 1 year on the basis of a medium-term plan and include mainly details of individual items from the medium-term plan. Medium-term plans are usually processed for a period

of 3 to 5 years and can be regarded as one of the key documents of internal audit. Internal audit plans based on the organizational structure are usually approved by the head of hospital. Internal audit must serve the management, thus a plan of activities should be showing real and actual problems of the organization. The plan should be a systematic process, not a one-time event. Good cooperation with the top management of organization, with the management of particular departments and department heads will facilitate and speed up the audit work.

From the planning point of view, internal audits can be divided into planned and exceptional. Planned internal audits are conducted in accordance with the medium-term and short-term internal audit plans, where is clearly stated what processes will be reviewed within the given deadlines. Exceptional internal audit is carried out mainly on detection of specific problems or any suspicion of process failure within the hospital.

An internal auditor keeps an audit file of the course of the audit which contains: - an order to perform the audit, an audit program, working documents, a report on the findings of the audit carried out including the recommendations from the Internal Audit Service (audit report), a record of the discussion about the internal audit report, a report on the implementation measures taken to remedy the deficiencies and recommendations of the IAS. The audit report is a result of research, investigations and analyses which were performed during the audit. The report summarizes in writing the internal auditor's opinion on the audited area.

Internal audit is not only a control activity but professional work necessary for good decisions. Therefore, it must provide a manager with accurate, complete, clear and reliable information. At the same time, however, the information must be transferred in an acceptable way. Decision-making errors are auditor's errors as well. Errors are likely to occur in an insufficient analysis, overestimation of trends, underestimation of certain events and facts. Internal audit plans are drawn primarily on the basis of risk assessment of individual activities in a hospital, the facts detected by previous audits or other monitoring activity, recommendations of head employees, major events in the administration and management of organization or information from external sources. [1], [2], [22], [23]

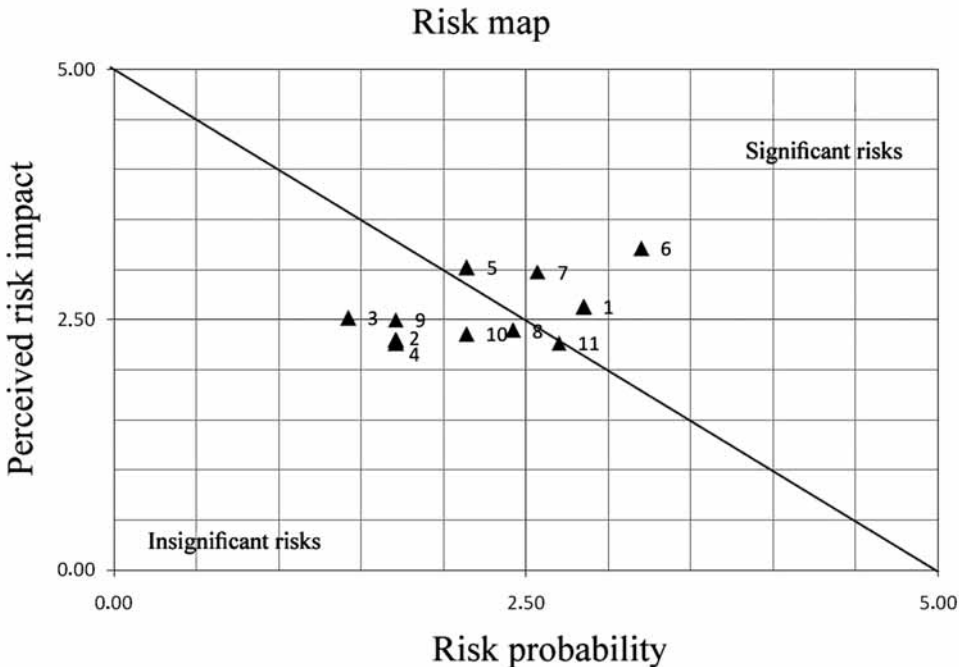
A risk can be considered as an event that may negatively affect the performance of hospitals. In this event it is possible to determine the probability of its occurrence and severity of its impact on the hospital. Risk assessment is one of the essential elements of risk management. Before proposing an appropriate method of risk management, a risk must be identified, evaluated and priorities have to be determined [19]. The objective of risk assessment is to estimate the likely consequences of threats on the basis of such analysis to take effective preventive measures to reduce the possibility of their occurrence or to minimize their impact. The main output of risk analysis is a risk map. The risk map is a clearly arranged document, which provides management with the information on risk management priorities according to their undesirable impact on the organization and the possibility of their occurrence. The output of risk analysis is to identify risk areas, assess risk and probability of its occurrence.

When assessing risks in hospital, the cooperation of an internal auditor with various departments primarily to assess the degree and

level of significance of individual risks in terms of their impact on the organization is very important. Questionnaires are usually prepared to be completed by managers of both health and non-health departments. The questionnaires focusing on health risk pay particular attention to physical, chemical, biological and combined risks. The questionnaires detecting non-health risks include questions on general risks, accounting and budget risks.

The following table (Tab. 1) shows the results of a survey assessing the significance of health risks in terms of their impact on the organization, which was conducted in one of Czech hospitals. The survey was conducted in 2007 using questionnaires. 47 hospital staff members on a variety of managerial positions participated in this survey. The significance of the risk was rated by survey respondents on a scale of 1 to 5, where **1** meant an **unnoticeable risk** of having a minimal impact on the organization, while **5** expressed an **unacceptable risk** with a very large impact on the organization (2 – exceptional risk, 3 – common risk, 4 – very important risk). In addition, the hos-

Fig. 2: The Risk Map of Health Departments (Risk Probability)



Source: own

pital top management (attended by 13 members of top management) established the risk probability (using the scale 1 to 5) on the basis of past experience and in accordance with the current processes in the organization. Upon the gained information, a risk map was prepared. (see Fig. 2).

The following part provides the results of survey and risk importance analysis. For your convenience, it is suitable to express the results of risk analysis in graphic form (Fig. 3).

The risks significance analysis shows that the most important risk for health departments is the biological risk of blood and tissue collection, manipulation with biomaterials in laboratories, storage of used needles, shards of ampoules, damaged

glass material, handling laundry used by patients. Given the frequency of these activities the risk probability increases with relatively large effect especially for hospital staff, which is related to the severity of treated diseases. Since the impact of this risk is very difficult to influence, we must focus especially on reducing the risk probability by using personal protective equipment and complying with recommended working practices. Other major risks are:

- Combined risk associated with manipulation with the patient as a potential source of transmitted diseases;
- Biological risk related to pathogenic bacteria, viruses, myotic fungi and non-microbial biological antigens;

Tab. 1: The Results of Survey on the Risk Importance for Health Departments (Part 1)

		Relative frequency					Total	Average	Risk probability
		Absolute frequency							
		1	2	3	4	5			
Physical risks									
1	Falls of staff and patients on the flat, stairs, from high places, manipulation with immobile patients. Falls of objects, instruments (scalpels, scissors...), materials.	8.70	26.09	58.70	6.51	0.00			
		4	12	27	3	0	46	2.63	2.85
2	Excessive heat/cold, open flames, excessive noise	23.40	38.30	25.53	10.64	2.13			
		11	18	12	5	1	47	2.30	1.71
3	Risk of electric shock, non-ionizing radiation (laser), ionizing radiation (RTG)	21.74	30.43	30.43	8.70	8.70			
		10	14	14	4	4	46	2.52	1.42
Chemical risks									
4	Excessive dust, smoke, steam, gases, injuries caused by handling chemicals	23.91	39.13	23.91	13.04	0.00			
		11	18	11	6	0	46	2.26	1.71
Biological risks									
5	Pathogenic bacteria, viruses, Myotic fungi, Non-microbial biological antigens.	8.51	14.89	44.68	29.79	2.13			
		4	7	21	14	1	47	3.02	2.14

Tab. 1: The Results of Survey on the Risk Importance for Health Departments (Part 2)

6	Blood and tissue collection, manipulation with biomaterials in laboratories, storage of used needles, shards of ampoules, damaged glass material, handling laundry used by patients.	0.00	19.15	42.55	36.17	2.13			
		0	9	20	17	1	47	3.21	3.20
Combined risks									
7	Manipulation with the patient as a potential source of transmitted diseases. Women apply to regulation 261/97 Coll.	4.65	25.58	39.53	27.91	2.33			
		2	11	17	12	1	43	2.98	2.57
8	Replacement of patients' medical records	32.56	37.21	4.65	9.30	16.28			
		14	16	2	4	7	43	2.40	2.42
9	Patients identity confusion	34.09	31.82	4.55	9.09	20.45			
		15	14	2	4	9	44	2.50	1.71
10	Known allergies not reported in advance	28.57	40.48	4.76	19.05	7.14			
		12	17	2	8	3	42	2.36	2.14
11	Unethical behaviour of medical personnel	26.46	40.40	20.00	6.57	6.57			
		12	18	9	3	3	45	2.27	2.70

Source: own

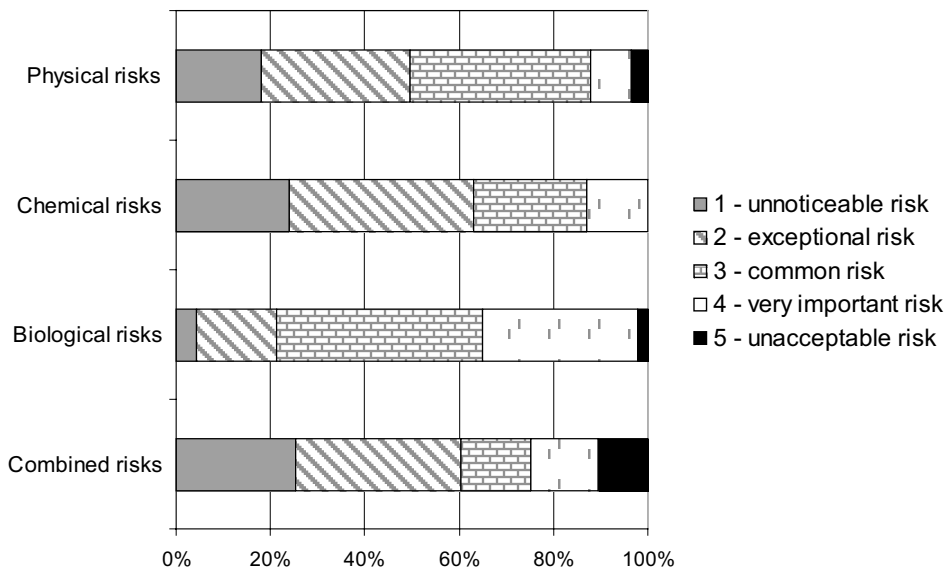
- Physical risk connected to falls of staff and patients on the flat, stairs, from high places, manipulation with immobile patients and falls of objects, instruments (scalpels, scissors...), and materials.

The survey in non-health departments assessing the significance of individual risks was carried out based on a similar methodology by twelve managers of non-health departments. Respondents also evaluated the risk significance on a scale of 1 to 5, where 1 meant an unnoticeable risk having a minimal impact on the organization, while 5 expressed an unacceptable risk with a very large impact on the organization. The risk probability in this case was not established. The results of the survey are summarized in the following table.

The structure of responses within each risk group can be expressed using the following picture (see Fig. 4).

The chart shows that the highest proportion of risk with a moderate and significant impact (assessed from 3 to 5) belongs to a group of general risk. As a significant risk is in this particular case evaluated the behaviour of employees in public (average rating 2.83), which has an essential impact on the image of the hospital as a whole and the perception by patients. The effort is to minimize this risk by constant appealing the hospital staff and by applying the general definition of employee code of behaviour. Increased attention should also be paid to the area of human resources and remuneration or provision of common tasks in health service, where an average rate is 2.5.

Fig. 3: The Significance of Risks for Health Departments in %



Source: own

Tab. 2: The Results of Survey on the Risk Importance for Non-health Departments (Part 1)

		Relative frequency					Total	Average
		Absolute frequency						
		1	2	3	4	5		
General risks								
1	Control and inspection activities - inspection, audit, management control	58.33	25.00	0.00	0.00	16.67		
		7	3	0	0	2	12	1.92
2	Business trips abroad	44.44	22.22	11.11	11.11	11.11		
		4	2	1	1	1	9	2.22
3	Provision of common tasks in health service	33.33	16.67	33.33	0.00	16.67		
		4	2	4	0	2	12	2.50
4	Conclusion of contracts (supply of goods and services, contract for work, rents and leases, etc.)	36.36	27.27	18.18	0.00	18.18		
		4	3	2	0	2	11	2.36

Tab. 2: The Results of Survey on the Risk Importance for Non-health Departments (Part 2)

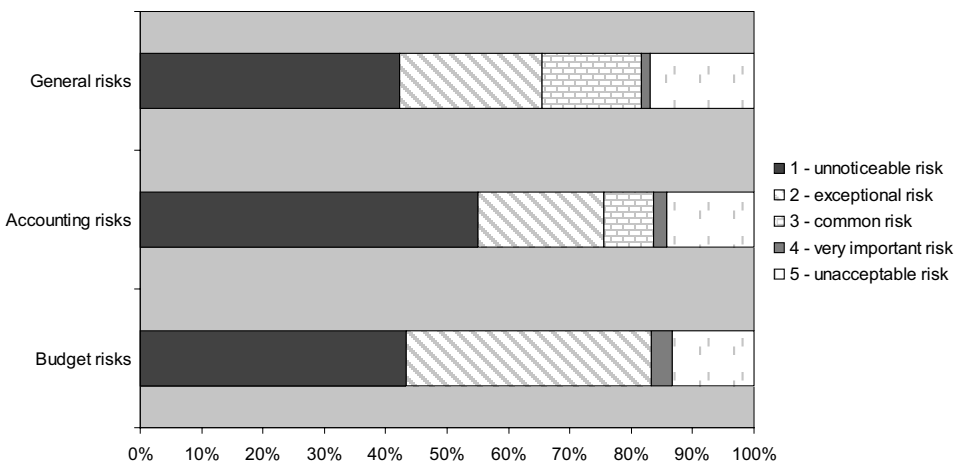
5	Public procurement – selection procedures	60.00	20.00	0.00	0.00	20.00		
		6	2	0	0	2	10	2.00
6	Concluding subcontracts and contracts of services	70.00	0.00	10.00	0.00	20.00		
		7	0	1	0	2	10	2.00
7	Remuneration of employees	25.00	33.33	25.00	0.00	16.67		
		3	4	3	0	2	12	2.50
8	Feast and material gifts	70.00	10.00	0.00	0.00	20.00		
		7	1	0	0	2	10	1.90
9	Legislative and legal affairs - representing organizations	40.00	20.00	20.00	0.00	20.00		
		4	2	2	0	2	10	2.40
10	Human resources – employee recruitment	25.00	33.33	25.00	0.00	16.67		
		3	4	3	0	2	12	2.50
11	Provision of organization's functioning, asset management, its use, maintenance, restoration, registration	50.00	25.00	8.33	0.00	16.67		
		6	3	1	0	2	12	2.08
12	Behaviour of employees in public	8.33	25.00	50.00	8.33	8.33		
		1	3	6	1	1	12	2.83
13	Behaviour of managers	40.00	40.00	0.00	0.00	20.00		
		4	4	0	0	2	10	2.20
Accounting risks								
14	Financial operations	54.55	18.18	9.09	0.00	18.18		
		6	2	1	0	2	11	2.09
15	Budget manager	54.55	27.27	9.09	0.00	9.09		
		6	3	1	0	1	11	1.82
16	Head accountant	33.33	44.44	11.11	0.00	11.11		
		3	4	1	0	1	9	2.11
17	Managing assets of Fund for Cultural and Social Needs	66.67	11.11	0.00	11.11	11.11		
		6	1	0	1	1	9	1.89
18	The area of the financial settlement of relations with the state budget.	66.67	0.00	11.11	0.00	22.22		
		6	0	1	0	2	9	2.11

Tab. 2: The Results of Survey on the Risk Importance for Non-health Departments (Part 3)

Budget risks								
19	Grants provided by the Ministry of Health of the Czech Republic	50.00	30.00	0.00	0.00	20.00		
		5	3	0	0	2	10	2.10
20	Provision of grants	44.44	33.33	0.00	0.00	22.22		
		4	3	0	0	2	9	2.22
21	Efficient use of resources	36.36	54.55	0.00	9.09	0.00		
		4	6	0	1	0	11	1.82

Source: own

Fig. 4: The Significance of Risks for Non-health Departments in %



Source: own

Methods and procedures in health departments must be revised periodically in order to minimize the probability and impact of identified significant risks, which mostly derive from the very nature of health facility and activities performed there. The audit should pay maximum attention to significant risks found. The auditor must not only address the risks, but also the conditions under which these risks arise, to be able to quantify, identify and distinguish the conditions of their origin that have to be eliminated. Further, the auditor draws from the process analysis, analyzes the development and follows directions, looks for regularities and may indicate a presumption based on the processes found.

In conclusion, we can say that during their existence internal auditors and Internal Audit have demonstrated the merits of inclusion in the organizational structure and management processes of hospitals. By now, perhaps none of the top managers in hospitals would doubt their contribution to the organization. Hospitals view the internal audit more often as a helper and mentor than as a means of repression and control. This trend is mainly due to high-quality work of internal auditors, their continuing professional education, the implementation of international quality standards in hospitals and last but not least the arrival of a new wave of hospital managers with economic and managerial education. Today, no one doubts

that the implementation of internal audit has led not only to higher effectiveness of all internal processes but also to improvement of care for patients in all hospitals.

Conclusion

The paper points out at current trends in management of health departments. The authors recommend the implementation of comprehensive Integrated Management System, which would also include risk management with the primary aim of improving patient safety. The experience in the monitored hospital showed the meaningfulness of internal auditors and their indispensable role in risk management.

Currently, this issue is one of the priorities of the Ministry of Health of the CR. It is a long-term process, which necessarily requires the active involvement of professionals as well as general public. A prerequisite for success is a change in management, thinking and behaviour of individual groups and their active effort to achieve the set objectives. Significant help to achieve these aims, among others, may be provided by the international standard ISO 31000:2009 [17], which is new and in the meantime tested in practice only little. Health services management is such a complex process that it can be assumed that the new standard will become an important part of the package with a variety of other tools, not only reducing the risks in relation to patients but also to all other components of the Integrated Management System.

The paper includes the results of a questionnaire survey from one of the largest hospitals in the CR, related to the assessment of significance of health and non-health risks in terms of their impact on the organization. 47 hospital staff members on a variety of managerial positions participated in this survey. Based on the survey results of and the set probability, a risk analysis was carried out.

The risk analysis shows that the most important risk for health departments is the biological risk of blood and tissue collection, manipulation with biomaterials in laboratories, storage of used needles, shards of ampoules, damaged glass material, handling laundry used by patients. Given the frequency of these activities the risk probability increases with relatively large effect especially for hospital staff, which is related to the severity of

treated diseases. Since the impact of this risk is very difficult to influence, we must focus especially on reducing the risk probability by using personal protective equipment and complying with recommended working practices.

The risk analysis shows that the highest proportion of risks with a moderate and significant impact (assessed from 3 to 5) belong to a group of general risks. As a significant risk is in this particular case evaluated the behaviour of employees in public (average rating 2.83), which has an essential impact on the image of the hospital as a whole and the perception by patients. The effort is to minimize this risk by constant appealing the hospital staff and by applying the general definition of employee code of behaviour. Increased attention should also be paid to the area of human resources and remuneration or provision of common tasks in health service, where an average rate is 2.5.

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ABSTRACT**RISK MANAGEMENT AND INTERNAL AUDIT IN INTEGRATED PROCESS MANAGEMENT OF HOSPITALS****Kristýna Keclíková, Petr Briš**

The paper focuses on the issue of improving patient safety, which is now a global issue. Foreign studies have shown that approximately 10 % of hospitalizations occur at patient's damage. The Czech Republic, respectively Ministry of Health of the Czech Republic, is currently developing a series of activities to promote the Luxembourg Declaration (Luxembourg Declaration on Patient Safety), which was approved at the EU Member States Summit and calls on the EU Member States to deal with this issue. This publication supports the above-mentioned activities. There is proposed the introduction of Quality Management System (QMS), which would include the risk management. Furthermore, there are described experiences from one large public hospital in the Czech Republic with incorporated certain features of risk management into the competency of internal auditors. A research took place to evaluate the significance of health and non-health risks in terms of their impact on the organization. 47 hospital staff members on a variety of managerial positions participated in this survey. The questionnaires surveying health risks paid particular attention to physical, chemical, biological and combined risks. The questionnaires researching non-health risks included questions on general, accounting and budget risks.

The risk analysis shows that the most important risk for health facilities is the biological risk of blood and tissue collection, manipulation with biomaterials in laboratories, storage of used needles, shards of ampoules, damaged glass material and handling laundry used by patients.

The risk analysis shows that the highest proportion of risk with a moderate and significant impact belongs to a group of general risk. As a significant risk is in this particular case evaluated the behaviour of employees in public, which has an essential impact on the image of the hospital as a whole and the perception by patients.

Key Words: process, risk management, integrated management system, internal audit, patient safety, analyse.

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