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EUROPEAN ORGANISATIONS FOR HEALTHCARE SUPERVISION - A COMPARATIVE ANALYSIS

ABSTRACT

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All supporting materials are available at the Secretariat of the Dean's Office of the Faculty of Public Health, MU - Sofia, University Hospital "Tsaritsa Ioanna - ISUL" EAD, 8 White Sea Str., Sofia.

Contents

1. INTRODUCTION

Ensuring quality medical services and patient safety is declared as a key priority of health policy, health administration, funding bodies, healthcare providers and consumers in the European Union and in the Republic of Bulgaria. According to the Glossary of semantic terms and definitions most commonly used in healthcare organisation and management, quality of healthcare is defined as "the degree of achieving the greatest benefit to human health without increasing health risk at an optimal balance between benefit and risk"[1] . If we go into the essence of this definition, we find that, on the one hand, quality of healthcare is associated with the provision of sufficient diagnostic and therapeutic activities to each patient to ensure the best health outcome in accordance with the current state of medical science. On the other hand, these activities should be provided at the best cost for this outcome and at the minimum risk to the patient, while achieving satisfaction with the activities/procedures, the results and the patient-doctor relationship.

Relatively new to the reality of Bulgarian healthcare is the medical audit. It is defined as "a systematic, critical analysis of the quality of medical services, including the procedures for diagnosis and treatment, the use of resources and the final outcome for the patient"[2]. By its very nature, medical audit is concerned with measuring and evaluating the activities of the healthcare provider by comparing them with established standards and suggesting measures for improvement in cases of identified non-conformities. It is this characteristic of medical audit that proves that the process of quality assessment in healthcare is a continuous and responsible process that is carried out by specific mechanisms. This is because the quality of the medical care provided is assessed in accordance with the medical standards in force. The assessment of the quality of medical care also depends on the Rules for good medical practice. Therefore, the activity of medical audit is carried out by means of a set of rules and regulations, but at the same time it is also subject to some fundamental principles, such as the principle that the patient must be placed at the centre of the system - the structure, organisation, staff, resources must be organised in such a way as to meet the needs of patients, in accordance with the level of morbidity, mortality, preventive activities, etc. Next is the principle according to which a horizontal system of interrelated processes should be provided, involving sequential steps and actions determining the outcome of treatment. The formula requires that the same results or those with minor variations are obtained in the same circumstances, reducing redundant processes but avoiding 'skipping' necessary steps. Third is the

[1] Prof. Dr. Z. Petrova, PhD, Dr. St. Genev, Ph. Enchev, A. Vodenicharova, Glossary of the most frequently used definitions, definitions, terms and acronyms in the theory and practice of public health, EC Print Ltd., Sofia, 2014.
[2] Prof. Dr. Z. Petrova, PhD, Dr. St. Genev, Ph. Enchev, A. Vodenicharova, Glossary of the most frequently used definitions, definitions, terms and acronyms in the theory and practice of public health, EC Print Ltd., Sofia, 2014.

principle that those working at all levels of the health system should be involved in quality assurance, i.e. everyone and anyone in the system should contribute to the quality of health care at that level. The logical and precise distribution of responsibilities for quality at national, regional, local and institutional levels is another principle. Consequently, bodies and institutions such as the Executive Agency for Medical Supervision, the National Health Insurance Fund, professional organisations of doctors', dentists' and health care professionals' are also involved to one degree or another in assessing, monitoring and controlling quality through the use of mechanisms to monitor patient satisfaction, by drawing up or participating in the drawing up of standards and rules and, where appropriate, monitoring compliance with them, by conducting training sessions for patients with chronic diseases, by actively working to improve the relationship and communication between doctor and patient, by assisting medical institutions in building internal quality control systems, as well as by developing methods for linking the quality of the activity with its financing.

The quality of healthcare should not be viewed only from the perspective of patient satisfaction, as such an approach would be one-sided. Quality should also be considered from the perspective of the healthcare providers. They must have, under certain clear rules, the capacity to apply modern methods and approaches to treatment, and to have access to innovative diagnostic and therapeutic solutions. Next, the quality of their activities also depends on the results of the structures in which they work and, respectively, the satisfaction and approval of the management. The process of achieving quality is an all-encompassing one, and therefore patients, through their organisations, as well as professional organisations and the educational structures in which doctors, dentists, health care professionals, etc., are trained, must be involved in it.

Creating a better and safer health system can only happen when all partners in health care - medical professionals, managers, patients, financial institutions and those who develop health policy - are involved in the process of change. On the one hand, this means that the efforts of all actors need to come together and, on the other, that the culture of communication between them also needs to improve.

2. PURPOSE AND OBJECTIVES

2.1. MAIN THESIS OF THE DISSERTATION

The main thesis of the study is the role and place of supervisory structures in assessing and improving the quality of medical services, to achieve the mission of any health system, to achieve an indivisible unity and interaction of health resources, management, quality of health care offered and health outcomes and satisfaction for the population.

The aim of the study is to analyze the experience in the field of (inspection) control in the countries of Europe and Bulgaria in order to improve the effectiveness of the healthcare control in the country and increase the quality and safety of medical services.

2.2. RESEARCH OBJECTIVES:

1. To trace the main theoretical and legal aspects related to the implementation of control as an element of management, on the quality of medical care.
2. To characterize the institutions exercising control in the health care system in Bulgaria.
3. To discuss and systematize information relevant to the ways and methods of control by the institutions involved in the European countries.
4. To analyze the activities of the Executive Agency "Medical Audit" for a three-year period (2016, 2017 and 2018);
5. To analyse the activities of the Executive Agency "Medical Supervision" as the successor of the Executive Agency "Medical Audit".
6. To propose options for improving the control based on the data from the analysis of the international survey and to make suggestions for improving the control in Bulgaria in order to increase the quality and safety of medical services.

2.3. OBJECT, SUBJECT AND METHODOLOGY OF THE STUDY

As a result of the set scientific tasks **the object of the** present study are:

- Normative documents (legal and sub-legislative) regulating control activities in the field of health care;
- Strategies for the development of control activities in health care;
- Methodologies, guidelines, rules for control;
- Reports on the results of control activities;
- Other

The subject of the study is the research of the control activity in the field of quality and safety of medical services in Bulgaria and seven European countries. Attention is paid to the place, role and importance of control for quality improvement in health care.

The study is complex. The first stage includes a study and analysis of the activities of the Executive Agency "Medical Audit" for a three-year period based on publicly available information and documentation, as well as the activities of its successor EAMS.

The second stage includes an analysis of the control activities carried out by similar organisations in seven European countries - England, Sweden, Estonia, France, Portugal, Finland and Denmark.

The third stage is a comparative analysis of the activities of the studied supervisory organizations in the health care system in Bulgaria and Europe and the impact of their activities on the improvement of the quality of medical services.

Research methodology

The dissertation aims to analyze the experience in the field of (inspection) control in the countries of Europe and Bulgaria in order to improve the effectiveness of the control of medical care in the country and increase the quality and safety of medical services.

In order to achieve these objectives, this study combines:

- Documentary method - normative documents, official reports and data, and scientific publications;
- Conceptual analysis - in order to clarify terminological issues related to the topic of the dissertation;
- Analysis of the activities of supervisory institutions;
- Comparative analysis;
- Graphical analysis - to visualize the results obtained.

Thus, the methods listed are complementary, allowing the information to be evaluated in a multifaceted way.

3. RESEARCH RESULTS

3.1. ANALYSIS OF THE ACTIVITIES OF THE EXECUTIVE AGENCY "MEDICAL AUDIT" FOR A THREE-YEAR PERIOD (2016, 2017 AND 2018)

The Executive Agency "Medical Audit" (EAMA) was established on the basis of Article 116a of the Health Act and started activities on 1 January 2010 as an administration under the Minister of Health. The agency is a legal entity on budgetary dependence - a secondary authorising officer. Territorially, EAMA covers the entire territory of the Republic of Bulgaria, has no territorial structures and the law does not currently provide for the establishment of such structures.

The Agency exercises control over the medical care of citizens and medical control over activities related to compulsory and voluntary health insurance. The Agency's powers include: carrying out checks on the compliance of the structure, management, operation and organisation

of medical services in medical establishments with the requirements of the Health Act, the Healthcare Establishments Act and the regulations implementing them; checks on compliance with patients' rights in healthcare establishments; checks on compliance with the established medical standards in healthcare establishments; carrying out checks on the quality of medical services in accordance with the established medical standards in healthcare establishments. The Agency monitors whether the National Health Insurance Fund provides the basic package of health care activities guaranteed by its budget and whether voluntary health insurance companies provide/pay for health care services in accordance with the health insurance contract. In addition to the above activities, the Agency: carries out inspections on requests from citizens and legal entities related to medical services, carries out activities to detect and prevent corrupt acts and practices in medical institutions, carries out inspections on the way medical institutions spend funds allocated to them by the national budget.

In order to track and analyze the activities of the Executive Agency "Medical Audit" for a three-year period (2016, 2017 and 2018) we review: the complaints and signals from individuals and legal entities for the period, the violations detected by the officials of EAMA and formulate conclusions from the control activities of EAMA.

In 2016, EAMA received a total of 664 complaints and signals from citizens and institutions. They were distributed as follows: from individuals - 298 (44.9%), from legal entities - 366 (55.1%). In 2017, 528 complaints and signals were received, distributed as follows: from individuals - 258 (48.9%), from legal entities - 270 (51.1%). In 2018, a total of 744 signals were received, distributed as follows: from individuals - 381 (51.2%), from legal entities - 363 (48.8%). When comparing the results obtained, it is noteworthy that the share of complaints and signals submitted by natural persons was the lowest in 2016 - only 44.9% of all complaints and signals received. In 2017, there was an increase in complaints from individuals, while 51.2% of all reports in 2018 coming from individuals. In terms of complaints and signals received from legal entities, the largest share of complaints was received from the Ministry of Health - 197 pcs. in 2016 or 53.8%, 155 pcs. in 2017 or 57.4% and 171 pcs. or 47.1% in 2018. There has been a significant increase in the number of complaints filed by the prosecution and Ministry of Interior affairs, with an increase of around and over 10% in 2018 from previous years. There is a steady trend of a smooth increase in the share of complaints filed by the Regional Health Inspectorates, with 29 complaints or 7.9% of the total number of complaints and signals received in 2016, an increase of about 3.2% in 2017, and a total of 35 complaints or 9.6% of all complaints filed in 2018. The remaining complaints and signals from legal entities hovered between 9%-15% of the total. The

structure of complaints and signals received by EAMA for the analyzed period can be seen in Figure 1.

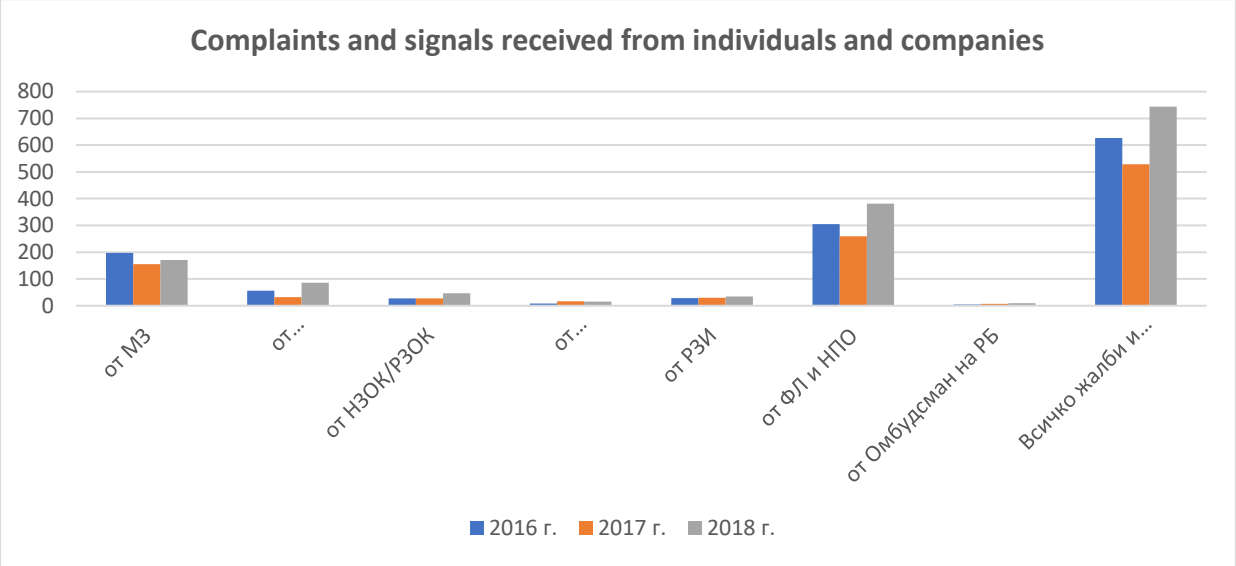

Fig. 1 Structure of complaints and signals received by EAMA for the period analysed

In 2016, EAMA officials carried out a total of 598 inspections, with 766 tasks, inspecting a total of 316 healthcare establishments, including 165 establishments for inpatient care and 145 for outpatient care. In 2017, EAMA carried out controls by conducting inspections in 651 sub-controlled facilities, with a scope of 781 audit tasks, 317 of which were in healthcare establishments. For 2018, inspections were carried out in **646** sub-controlled facilities, with a scope of **778** audit tasks, 594 audit tasks were in hospital care facilities and 170 audit tasks in outpatient care facilities.

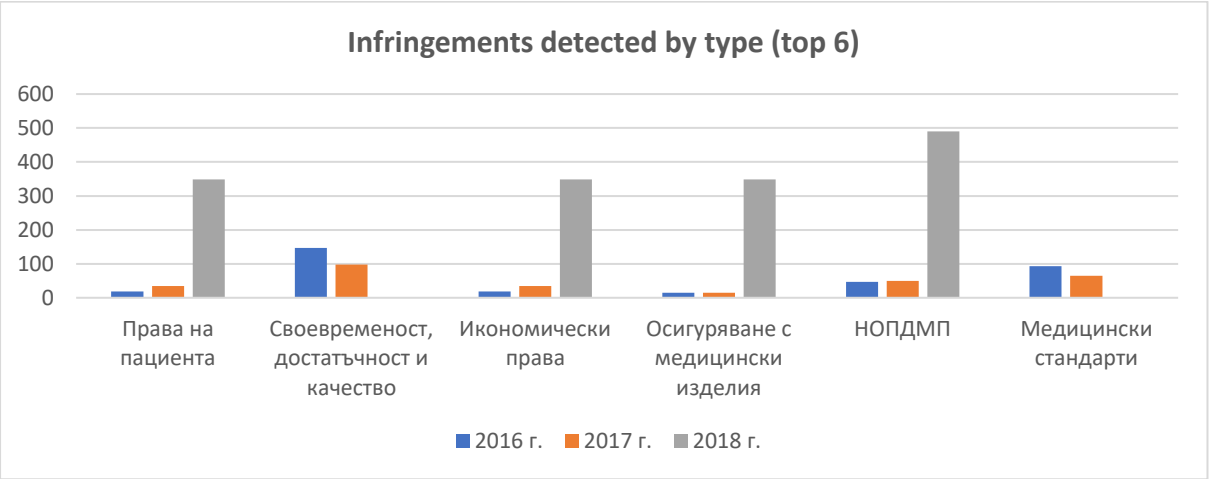

Fig. 2 The most common types of infringements found

In order to remedy the identified deficiencies, EAMA staff provide on-the-spot methodological assistance and make appropriate recommendations, and in case of more serious violations, take measures in accordance with the Agency's powers. Where a problem is identified in the quality of medical care provided, the Agency's inspectors react immediately by making recommendations for improvement. In cases where more serious deficiencies and breaches are observed, measures are taken in accordance with their statutory powers, i.e. the appropriate administrative proceedings are initiated. In the overwhelming number of cases, the reports drawn up as a result of the inspections carried out are accepted by the management of the healthcare establishments as an objective and impartial analysis of their activities, the shortcomings identified and proposals for their elimination. The healthcare establishments themselves face challenges in making improvements in the organisation and management of the diagnostic and treatment process. The healthcare establishments inform the Agency of the actions taken and of the implementation of the recommendations made.

3.2. STRUCTURE AND COMPOSITION OF THE EXECUTIVE AGENCY MEDICAL SUPERVISION[3]

The Executive Agency "edical Supervision is the successor of the Executive Agency "Medical Audit". In 2019, the Executive Agency Medical Supervision (EAMS) was established through a merger of the Executive Agency for Medical Audit and the Executive Agency for Transplantation. The Agency is a legal entity on budgetary dependence - a secondary authorising officer with budgetary appropriations to the Minister of Health, with its seat in Sofia. The Rules of Procedure shall determine the organisation of the activities, functions, structure and composition of the Executive Agency Medical Supervision.

The Agency exercises permanent control over the medical services provided to citizens, compliance with established medical standards and patients' rights, and activities related to compulsory and voluntary health insurance.

EAMS shall exercise permanent control. It carries out continuous inspections to improve the quality of healthcare and safety for every patient. The Agency immediately notifies the employer, occupational safety authorities, environmental protection authorities to take the necessary measures in cases where working conditions and other harmful environmental factors that threaten the health of citizens are found**.**

[3] Rules of Procedure of the Executive Agency "Medical Supervision" in force since 01.04.2019, adopted by the PMS No. 53 of 27.03.2019, promulgated by. No. 26 of 29 March 2019

3.2.1. ORGANISATION OF WORK IN THE EXECUTIVE AGENCY MEDICAL SUPERVISION

In accordance with their functional competences[4], the Agency's units shall interact with each other in carrying out tasks that are the responsibility of more than one structural unit.

In order to improve the control activities and to increase their quality, the Executive Director's order establishes committees of staff from different directorates to carry out inspections, thus achieving a flexible allocation of human resources in the Agency.

3.2.2. SYSTEM OF MEDICAL SUPERVISION[5]

The object of control are all natural and legal persons providing medical and dental care under the Healthcare Establishments Act (HEA) and the Organ, Tissue and Cell Transplantation Act, as well as the NHIF/RHIF and the insurers under art. 83, par. 1 of the HIA on the territory of the Republic of Bulgaria.

The Agency carries out planed and unplaned inspections. Depending on the method of inspection, inspections may be carried out on site at the inspected establishment or on documents on the premises of the Agency. Planed inspections may be full or thematic. The Agency may carry out self-referral inspections as well as joint inspections involving other persons or institutions. In carrying out its activities, the Agency also carries out simultaneous inspections with the Ministry of Health (MoH), the Bulgarian Drug Agancy, the Regional Health Inspectorates (RHI), the NHIF/RHIF, and other state bodies. In carrying out its functions and tasks, the Agency also interacts closely with other central and local executive authorities. In exercising the powers thus conferred, it is expected that the Agency will work towards continuous improvement in the quality and safety of medical care for citizens. This will also stimulate changes in health care to ensure that Bulgarian citizens have access to quality, safe and effective medical care.

3.2.3. ORGANISATION AND PERFORMANCE OF THE EAMS INSPECTIONS

At the time of the study, there were no internal rules organizing the control activities of the EAMS. In the absence of such rules, and taking into account the fact that the newly created agency is the successor of the EAMA, this section will attempt to compare the control activities carried out by the EAMS with those carried out by the EAMA on the basis of information publicly available in the reports on the activities of both organisations in terms of the number of complaints and signals, whistleblowers and violations.

[4] Rules of Procedure of the Executive Agency "Medical Supervision" in force since 01.04.2019, adopted by the PMS No. 53 of 27.03.2019, promulgated by. No. 26 of 29 March 2019

[5] Ordinance No. 1 of 26.03.2019 on the conditions and procedure for carrying out inspections by the Executive Agency "Medical Supervision" Issued by the Minister of Health, promulgated in State Gazette No. 26 of 29.03.2019, in force on 1.04.2019.

The control activity of the Executive Agency Medical Supervision is regulated only in the Ordinance No. 1 of 26.03.2019 on the conditions and procedure for carrying out inspections by the Executive Agency Medical Supervision, issued by the Minister of Health (promulgated by SG No. 26 of 29.03.2019, in force on 1.04.2019). The lack of an internal regulation describing in detail the methodology of inspections by inspectors is reported as a very serious shortcoming in the activities of the body carrying out control over the quality of medical services. On the one hand, the lack of a regulation implies that the inspecting officers have to make their own judgements and take certain actions, which may be different in the case of identical inspections, given that they are generally carried out by different teams, and on the other hand, it puts the inspected entities on an unequal footing, again for the reasons outlined above. The powers of EAMS are laid down in article 7b of the Healthcare Establishments Act. It is noteworthy that the competences of EAMS, compared to those of EAMA, are considerably extended. Their scope generally includes competences related to the registration of outpatient medical establishments as well as the activities of the competent authority for the management, coordination and control of transplantation in the Republic of Bulgaria in accordance with the Organ, Tissue and Cell Transplantation Act. The powers of EAMS related to the control of the quality of medical services are identical to those of EAMA. It should be noted as a positive change the introduction for the first time of the possibility for EAMS to issue mandatory prescriptions to healthcare establishments, the non-compliance of which is attached with a sanction.

After the transformation of EAMA into EAMS in 2019, the total number of complaints and signals submitted to EAMS in 2019 was 741, distributed as follows: from individuals - 402 (54.3%), from legal entities - 339 (45.7%). There is a preservation of the 2018 level, with a continuing trend towards an increase in the proportion of complaints and signals submitted by natural persons at the expense of those submitted by legal persons. In 2019 there has been an increase of nearly 3%. In terms of complaints and signals received from legal entities in 2019, there was a steady trend, with again the highest share of complaints received from the Ministry of Health - 171 pcs or 47.1%. Complaints from the prosecutor's office, the Ministry of Interior Affairs and the investigative bodies are again the second most frequent - 72 pcs. or 21.2% for 2019. A slight decrease compared to 2018 is observed. The remaining complaints and alerts from legal entities maintained the levels of previous years. The structure of complaints and signals received by the EAMS for the period under analysis can be seen in Figure 3.

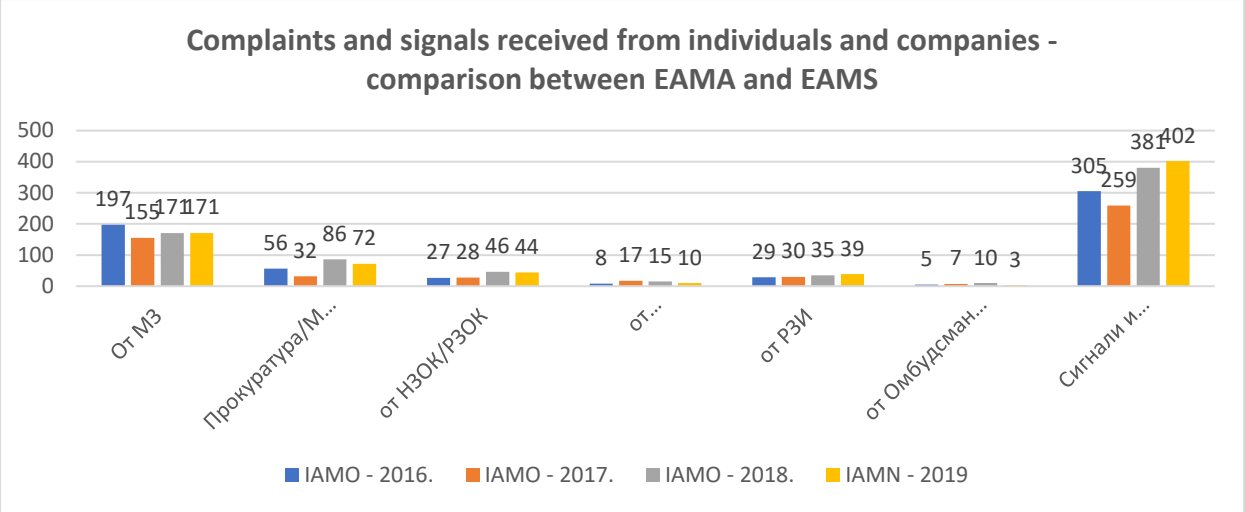

Fig. 3 Structure of complaints and alerts - EAMA-EAMS comparison

We have also followed the administrative and punitive activity of the agencies for the years under review. We used information from the annual activity reports of both agencies, Figure 4. The steady trend in the number of administrative penalty proceedings initiated in 2016, 2017 and 2018 changed in 2019, when a significant decrease in the number of proceedings initiated was recorded. At least two reasons can be given for this outcome - improvements have been made in the quality and safety of medical care for citizens, sustained improvements have been made in the performance, quality and professionalism of the sector, or the agency merger that took place in 2019 has affected the organisation of work in the newly created agency. We are more inclined to accept the second reason as more likely, taking into account that in 2019 there has been an increase in the number of complaints and reports filed by citizens and a steady trend in the number of complaints filed by legal entities.

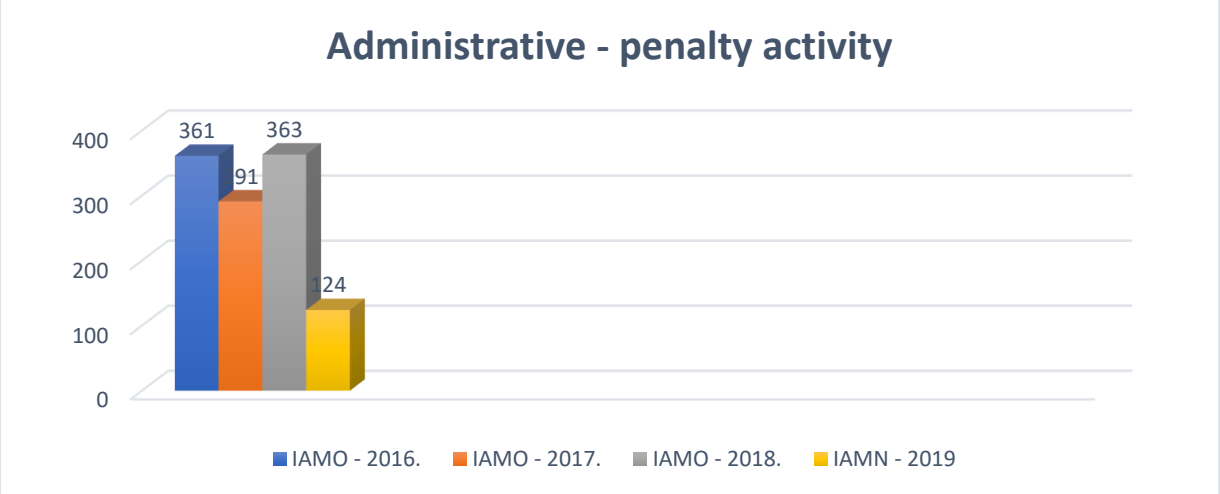

Fig. 4 Administrative - penalty activity - EAMA-EAMS comparison

The most frequently detected violations are related to the violation of the principle of timeliness, sufficiency and quality of the provided medical care, failure to provide the patient with the necessary information about the possible risks of the treatment, as recommendations for follow-up in this regard are not made, improper payment for medical services, incomplete medical documentation, violation of patients' rights in the selection of the doctor/team, etc.

As a result of the monitoring of the quality and efficiency of medical services, the following most frequent shortcomings in the activities of medical specialists and healthcare establishments are identified:

1. Medical care is not provided in a timely or sufficient manner, leading to late diagnosis and delay in treatment of patients. The gap identified indicates that established algorithms of good medical practice are not being followed.

2. Incomplete medical documentation, which means that there is no evidence of the activities performed by the medical specialists, and in a significant percentage of cases leads to a disruption of the continuity of the treatment and diagnostic process.

3. Lack of informed consent given after direct communication between patient and treating physician. The process of completing and signing informed consent is formal.

4. Infringing on the economic rights of patients by unlawfully demanding payment for medical services and/or medical devices.

3.3 SUPERVISORY ORGANISATIONS IN EUROPE

Western European countries have been steadily reforming their health systems over the last twenty-five years. The common elements of these reforms can be identified in the following way: Striving to bring health care spending into line with existing resources, which are generally limited. In contrast to the explosive growth in the post-World War II period, economic growth rates declined in the 1980s and 1990s, and health spending tended to "consume" an increasing share of gross domestic product (GDP). For this reason, individual countries have been prompted to take various measures to keep medical costs within reasonable limits, while at the same time ensuring that medical care continues in line with the growing demands of the population. Undertaking reforms to make healthcare a fairer system. It is common knowledge that health care should be offered equally and that providing a minimum package of health services for the whole population has its positive consequences. Nevertheless, it is a fact that access to medical care remains unequal in a number of countries, which is exacerbating social problems.

Reforming the health sector to improve the efficiency and quality of services. Different reforms are taking place in different countries. In countries where inefficiencies are assumed to be due to the absence of competition, measures have been taken to create competitive pressures. On the other hand, in systems where there is an oversupply of services, measures have been taken to introduce incentives for health care providers. All health insurance systems in the European Union rely on heterogeneous sources of funding, which are, however, controlled - directly or not - by the state.

The study is based on information from national institutions involved in the medical audit process. The information has been collected by different methods, including research and analysis of publicly available documents - legal acts, websites of the studied institutions, results of the Project "Social Innovations in the Executive Agency "Medical Audit"[6], etc. Whenever possible, the information collected was verified by several sources to ensure its completeness, accuracy and veracity.

The problem of ensuring the quality of medical services and patient safety is a priority for many countries. This section will examine the organisations involved in quality control of medical services in England, Denmark, Portugal, Sweden, Finland, Estonia and France. The selected countries have traditions in the field of quality of medical services and patient safety, and have institutions in place that are similar in function to those of the EAMS. The selected countries are excellent examples of how the authorities dealing with quality control of medical services are actively and continuously developing and implementing new control mechanisms aimed at achieving improvements in their health systems.

To achieve the objectives of the study, the following information will be examined in detail and comprehensively:

- The regulatory framework governing control activities in each of the countries studied;
- Organisations and institutions involved in control, structure, powers and responsibilities;
- Organization of control activities - planning, execution, reporting and analysis of results.

[6] Project "Social Innovations in the Executive Agency "Medical Audit", financed by the Operational Programme "Human Resources Development", 2014-2020, co-financed by the European Union through the European Social Fund, contract registration number: BG05:9OP001-4.001-0079-C01

3.3.1. ENGLAND

The Care Quality Commission (CQC) is the adminstration that is involved in the oversight of health and social care providers in England. The functions[7] of the CQC are principally set out in the Health and Social Care Act 2008 and the 2012 and 2014 amendments to that Act. Separate functions and powers are also set out in other legislation and regulations.The responsibilities of the CQC in a complex health and social care environment are wide ranging with the main task being to ensure the safe and effective delivery of health and social care services to citizens, alongside promoting and improving the care provided. The population is living longer and needs complex and long-term care, with the need for additional care increasing with age.

The committee's work is focused on regulation to ensure safe, high-quality care for more people[8]. Following its strategy, the commission has defined four main priorities on which it focuses its work:

1. Promoting improvement, innovation and sustainability in care;

2. Introducing new evidence-based approaches and data analysis into the regulation and supervision process;

3. Promoting a single shared vision of quality of service delivery;

4. Improve efficiency and effectiveness.

The Commission's governance structure[9] consists of two bodies:

1. **The Council** is the supreme decision-making body. It meets 11 times a year, with its main functions being to provide leadership and ensure the success and sustainability of the Commission. The Council is also the body that sets the strategy, purpose and values of the Commission.

2. **The Executive Board** is a collective body engaged in the operational activities of the Commission. It monitors the achievement of the objectives set out in the business plan and is responsible for the proper use of the Commission's resources. The Executive Board also manages and is responsible for the implementation of the objectives and activities within the remit of the Commission.

The focus is on the following activities:

Registration - looking for evidence relating to the applicant's compliance with regulatory requirements, taking into account the selection of an appropriate management team.

[7] http://www.cqc.org.uk/sites/default/files/20151111_Coporate_Governance_Framework_August_2015.pdf
8 Care Quality Commissions , Shaping the future: the CQC's strategy for 2016 to 2021, https://www.cqc.org.uk/file/384235
[9] http://www.cqc.org.uk/about-us/how-we-are-run/how-we-are-run

Inspection and evaluation - inspections focus on the quality and safety of the services provided by examining five key aspects:

- Safety of services offered;
- Efficiency of services offered;
- Good attitude and care;
- Services meet people's needs;
- Good result from the offered services.

Checklists of questions have been developed to assist the inspection teams in assessing the quality of services provided. These help to determine a rating for each of the five key aspects and where applicable an overall rating for the service offered. A four-level rating scale has been developed:

- Outstanding;
- Good;
- Requires improvement;
- Inadequate.

The mechanism for carrying out inspections and assessing services is detailed in guidance documents which are intended for providers of services and healthcare and which are designed to help them meet the requirements. The information in the guidance documents is tailored to the specificities of each sector and focuses on the details relevant to that sector. Indicators have been developed for each of the five key aspects which provide the framework which, together with the professional judgement of inspectors, assist in determining the assessment of the services offered. An important part of the model applied by the CQC to assess the overall quality of care offered is the use of the rating system and the focus on looking for 'good' practice. The requirements for 'good' and 'outstanding' ratings set out in the guidance go beyond the basic standards set out in the regulations while also monitoring their implementation. It is accepted that the rules set out in the regulations are a clear minimum standard that registered providers and their managers must meet, with failure to meet them allowing the CQC to take enforcement action against offenders (registered providers and managers who do not comply with).

The Commission uses a four-step process in its decision-making, which includes an initial assessment, legal and evidential analysis, selection of appropriate actions and a final review.

A priority in the Quality Commission's strategy for 2016-2021 is the use of evidence-based methods and analysis of data collected in the process of monitoring and regulating registered

services[10] . There is a shared understanding that the data collected from inspections will outline a clearer framework for the quality of health and social care, as well as answering the question of which data is most informative.

The data from the checks and inspections carried out are crucial for the Commission to work optimally. Aggregating the information received from service users, from the results of inspections and from data from partners enables the Commission to better organise its work, which in turn leads to more accurate reporting on changes in the quality of services provided.

The Commission monitors quality through a computational model, whereby all new services are mandatorily inspected and risk levels determined. Subsequent inspections focus on areas where the model indicates high risk or a need for quality improvement. In the event that changes in rating level are identified, an update of provider ratings is also carried out. The model used facilitates a better organisation of inspections and helps to validate good practice whilst making it easier for the Commission to identify poor quality services that need improvement. Furthermore, the approach used allows for better organisation of unannounced inspections as well as helping to build a common understanding of service quality.

Monitoring, risk indicators for quality of care. Risk assessment

In 2013, McKinsey & Company and the CQC, following extensive consultation, proposed approximately 150 indicators of quality of care on which to base a risk score[11]. The indicators cover a range of areas including mortality, waiting times, whistleblowing reports, staff and patient surveys and more. They relate to the five key aspects that all services must meet - safety of services provided, effectiveness of services provided, good treatment and care, care meets people's needs, good governance. In order to comply with the principle of openness and transparency, the Care

[10] Griffiths A, Beaussier A, Demeritt D, et al, Intelligent Monitoring? Assessing the ability of the Care Quality Commission's statistical surveillance tool to predict quality and prioritise NHS hospital inspections
BMJ Qual Saf 2017;26:120-130., https://qualitysafety.bmj.com/content/26/2/120

[11] CQC. Quality and Risk Profiles: Statistical Guidance, Outcome-based risk estimates in QRPs produced for NHS providers. 2013,
http://www.cqc.org.uk/sites/default/files/documents/20130314_nhs_statistical_guidance_march_2013_for_publication.pdf

Quality Commission provides full details of each of the indicators used in the model, explaining in detail the choice of each individual strand to be regulated by the Commission [1213].

The results of the analysis do not provide an assessment of the care provided, but are an indication of the level of risk. Combined with information from partners, the public, users and the available databases of analysed outcomes, it determines when, where and what to inspect. The results of the inspections are used to inform the ratings for each of the regulated areas. The Commission determines the specific evaluation criteria against which each indicator is assessed. For each indicator, a three-level scale is used:

- 0 ("No evidence of risk"),
- 1 ("Risk"),
- 2 ("Increased risk")

Statistical analysis and practical use of the system, combined with the well-established best practices of the EPSO[14] Risk Working Group, help the Commission to identify the most relevant indicators for hospitals.

3.3.2. FINLAND

The social and health systems in Finland are functionally linked, with the Ministry of Social Affairs and Health leading them. The Ministry's competences include preparing legislation in these areas as well as implementing it, setting guidelines for social and health policies, preparing major reforms in the sectors, coordinating and leading their implementation, leading and guiding the development of social and health services and overseeing them.

The provision of services to citizens is carried out by a wide range of public social and healthcare organisations as well as private companies. The organisation of social and healthcare at local level is the responsibility of municipalities, which can also purchase social and health services from other municipalities, organisations or private service providers. The management and monitoring of municipal and private social and healthcare, as well as the evaluation of the quality of municipal services, is carried out by Regional Government Agencies. Their scope of activity also includes the granting of licences to private service providers in the region concerned.

[12] CQC. Intelligent Monitoring: NHS Acute Hospitals Indicators and Methodology-May 2015: Care Quality Commission. 2015 (21 July 2015).
http://www.cqc.org.uk/sites/default/files/20150526_acute_im_v5_indicators_methodology_guidance.pdf

[13] Care Quality Commissions, Intelligent Monitoring NHS acute hospitals Indicators and methodology Guidance to support the July 2014 Intelligent Monitoring update

[14] European Partnership for Supervisory Organisations in Health Services and Social Care http://www.epsonet.eu

The National Welfare and Health Inspectorate VALVIRA[15] was established under the Ministry of Welfare and Health and is responsible for overseeing welfare and healthcare, as well as carrying out oversight under the Alcoholic Beverages and Public Health Protection Act. It is the body that issues licenses to health professionals who check the quality of water in public and private swimming pools; to manufacture, import, wholesale and retail alcohol; to private social and health care providers; to tissue banks, to embryo research, and licenses under the Assisted Reproductive Treatment Act, adoptions, etc. VALVIRA carries out national oversight of social care professionals and social care organizations, registered medical professionals, and healthcare facilities. VALVIRA's scope of activity also includes the control of the safety and compliance of medical devices.

The supervision that VALVIRA carries out over the services provided by medical professionals and healthcare establishments is mainly by giving instructions and carrying out inspections and can be divided into four categories - Follow-up monitoring of specific cases (e.g. in the case of complaints from patients), planned inspections based on national or municipal planning, instructions and advice to medical professionals and healthcare establishments and issuing opinions for other public institutions or for judicial ones.

In Finland, self-monitoring of healthcare facilities is particularly relied upon to ensure the safety and quality of healthcare services. It is assumed that the employer is responsible for controlling its own activities and staff and can therefore take immediate corrective action when non-compliance is found. Self-monitoring by service providers themselves is and should be the most effective form of supervision. An approach has been adopted which assumes that the role of VALVIRA is to offer support and guidance to social and healthcare providers in carrying out self-monitoring. Because of this model of supervision, VALVIRA issues detailed guidelines and instructions and is responsible for maintaining a national bank of quality indicators that are applicable to the self-monitoring process. Next, VALVIRA places particular emphasis on promoting effective, proactive and interactive supervision based on risk assessment.

Routine on-site inspections of the facility are conducted using the risk assessment model to achieve the most appropriate allocation of resources. The risk assessment mainly considers indicators related to patient safety. Next, active work is being carried out on the implementation of so-called 'interactive supervision', which is characterised by a shift in the focus of supervision from sanctioning and punishing to promoting dialogue and cooperation through meetings, discussions, information sharing and feedback.

[15] http://www.valvira.fi

In addition to Valvira, in Finland, the activities of healthcare institutions and medical professionals are controlled by the independent regional administration (AVI). The competences of the regional agencies are clearly defined at legislative level and Valvira exercises methodological guidance over the regional agencies in order to achieve harmonised licensing, administrative and supervisory practices in Finland's social and healthcare system. The AVIs are the main local supervisory authorities and thus complaints against healthcare providers are primarily handled by them. Valvira, on the other hand, mainly handles complaints related to the treatment of severely and permanently disabled patients or deaths where medical error or malpractice is suspected. Valvira's primary function is the supervision of healthcare where there are problems of a systemic nature, as well as activities that take place nationwide or in the area of several regional agencies.

The supervision activities carried out by Valvira and the regional agencies are in accordance with the programmes they have drawn up for the supervision of social and health activities.

Complaints and grievance system based on an internal self-monitoring system

The established system for the submission of complaints and grievances by patients is the main way of their participation in the system of control of healthcare institutions and medical professionals. When a patient or a close relative is dissatisfied with the medical care or treatment provided, he or she has the right to lodge a complaint with the Finnish health care supervisory authorities. This right can be exercised by all persons treated in Finland, regardless of their nationality and citizenship.

It is characteristic of the Finnish healthcare system that the problem of patient dissatisfaction with the treatment and care provided is very often solved at the level of the healthcare facility, as patients are advised to first have a conversation with the staff at the facility before filing a complaint with the supervisory authorities. If the outcome of the discussions is unsatisfactory for the patient, he/she can submit a so-called 'complaint' to the head of the facility concerned. If the review of the objection reveals that the care or treatment has resulted in harm to the patient, the patient is advised of the possibility of reporting the harm and how to claim compensation. Notwithstanding his right to object, the patient has the right to lodge a complaint, which is sent to the regional administration or to Valvira, depending on their jurisdiction. In Finland, there is no link between claims for compensation and complaints relating to the quality of medical services provided.

A key role has been played by the introduction of a obligation for each unit in the healthcare system to appoint a so-called 'patient ombudsman' whose main obligation is to protect the interests of patients in general. Part of the ombudsman's role is to promote and enforce patients' rights, and to contribute to improving the quality of care by advising patients and their relatives on issues relating to good care and appropriate treatment. It helps patients to resolve possible problems with the healthcare facility, including when filing a grievance, an appeal, or notifications of disability. His opinions and positions are advisory and impartial, he does not comment on medical decisions, does not evaluate the possibility of patient harm, and has no authority to interpret patient records.

Reform of the national supervisory authority in the context of the ongoing reform

In the area of state supervision in Finland, a huge change is foreseen, which will result in the establishment of a single State Licensing and Supervision Authority (Luova), which will bring together all licensing, control and supervision activities within the scope of 8 ministries, which are currently carried out by the current regional government agencies, ELY centres, KEHA Centre, Valvira, Melala Pension Agency, etc. The mandate of the newly created government body will include the areas of education and culture, social and health services, environment and employment.

Luova, as a national and multidisciplinary public authority, will ensure the coherence and availability of services, regardless of the territorial location of their provider, while at the same time it will have to ensure/guarantee the realisation of citizens' fundamental rights and monitor legal security throughout the country. It is assumed that the restructure of the supervisory bodies into a single multidisciplinary body will enable good practices of patient participation and involvement in the supervision process to be implemented in full and at every stage of the process, which is the reason why the results of this approach should be carefully monitored over time and used as a model for future organisational change.

3.3.3. DENMARK

There are two main administrative authorities in Denmark that are involved in promoting development and initiatives in social services:

- The National Board of Social Services (NBSS) and
- The Danish Patient Safety Authority (DPSA).

National Board of Social Services - NBSS

The Board is a government agency under the Ministry of Children and Social Affairs. The purpose of the Board is to actively promote knowledge-based social policy that supports effective

social initiatives for the benefit of citizens. The National Board for Social Services promotes various social service initiatives, assists and advises local authorities in the provision of services to citizens.

The National Board for Social Services is responsible for the following major social areas:

- Children and adolescents;
- People with disabilities, benefits and psychosocial initiatives;
- Elderly people with social problems, groups at risk.

Some of the tasks of the National Board on Social Services include providing new knowledge in the field of social science, promoting effective social and scientific practices, supporting social welfare councils in municipalities, regions and citizens, as well as supporting the development and implementation of social policy, and managing subsidy schemes.

The motto of the National Board for Social Services is **"We make knowledge useful"[16] .** To this end, a knowledge sharing portal has been created to make it easier for people working with social care issues as it is aimed at managers, advisers and professionals employed in local government and providers[17]. The portal also provides up-to-date knowledge on vulnerable groups as well as people with disabilities, information on both Danish and international research can be found there.

Danish Patient Safety Agency - DPSA

The main objective of the Danish Patient Safety Agency is to ensure patient safety and support training in the healthcare sector. On the basis of an ongoing risk analysis, areas of highest risk to patients are identified and resources are allocated to them, thereby achieving the highest possible level of patient safety. The expectation is that the DPSA will be able to identify high risk situations and thereby help to improve operations in the health sector. For this reason, in 2017 the Agency introduced a new model for risk-based supervisions. An integral part of the DPSA's activities is training, which uses the results of the DPSA's supervisions[18].

The Danish Patient Safety Agency is responsible for a number of tasks included in the Greater Patient Safety Strategy[19], such as the supervision of health professionals and healthcare organisations (medical institutions), advice on communicable diseases, health status related to

16 https://socialstyrelsen.dk/om-os/Strategi-mal-og-resultater/strategi/ Strategy 2020, Social Board's strategy (pdf)

17 https://vidensportal.dk/

18 https://stps.dk/da/

19 https://stps.dk/da/om-os/maal-og-opgaver/

driving licences, as well as assistance in conducting investigations, registration of local and foreign healthcare professionals, issuing of permits for independent practice

Denmark uses a model of quality management in healthcare and patient safety assurance that puts it at the forefront of efficiency in healthcare services and patient care. Information sharing and continuous learning[20] together with the use of new electronic technologies and innovations make Denmark a highly relevant example that deserves attention.

In 2004, a special Patient Safety Act was adopted. The Act requires all healthcare providers to electronically report all adverse events/incidents related to the treatment provided. The law provides assurances that reporters will not be prosecuted for the information they report by anonymizing the data and analyzing it regionally and globally. The focus is on identifying risks and negative trends so that timely and preventive measures can be taken.

The DPSA[21] registers and monitors the activities of general practitioners and supervises the activities of healthcare establishments, as well as carrying out inspections following complaints from patients. The DPSA is responsible for administering the adverse event/incident reporting system. It uses the information from the system for analytical purposes, and on this basis develops guidelines and recommendations which it disseminates to healthcare stakeholders and GPs for preventive action.

In collaboration with a medical professional and external stakeholders, risk assessment indicators are determined. The aim is to ensure that they are relevant in the first place and furthermore approved by the stakeholders.

The Agency's 2019 Strategy focuses on the following operational objectives:[22]

- Risk-based supervision
- High quality and short service time
- Sharing knowledge for learning
- Synergism and coherence in core services and activities
- Develop clear health, legal and administrative competencies
- Active stakeholder management, including communication with the public.

The new risk-based supervision model introduced in 2017 will be implemented over a three-year period[23][24]. During this period, the agency must create a baseline risk profile for each

[20] https://stps.dk/da/
[21] Danish Patient Safety Authority https://stps.dk
[22] https://stps.dk/da/om-os/maal-og-opgaver/strategi-2019/
[23] https://stps.dk/da/sundhedsprofessionelle-og-myndigheder/det-risikobaserede-tilsyn/
[24] Styrelsen for Patientsikkerhed, Strategi for tilsyn Styrelsen for Patientsikkerhed, December 2017, https://stps.dk/da/udgivelser/2017/strategi-for-tilsyn/~/media/107551FC9BF54B68920F712FCA9440B2.ashx

type of healthcare facility that will aim to identify high-risk areas to be audited. The DPSA's more distant goal is to develop a method for assessing the risk of individual institutions, as risk analysis is currently only used to identify high-risk areas. The risk-based supervision model assumes that the majority of the agency's activities will be focused on providers that present the highest risk to patient safety. Based on a proactive risk analysis that is informed by complaints and surveys of patients, relatives and health officials and the results of surveys conducted by other public authorities, the patient safety agency oversees selected public and private healthcare facilities where the greatest risk to patient safety has been identified. Each inspection concludes with the preparation of a report that contains the results of the supervision conducted on the provider's operations and the presence of violations and patient safety hazards. On an annual basis, the Agency prepares a summary report containing information on the inspections performed as well as the assessments made as a result of the risk-based control. In view of the objective impossibility of visiting all the inspected establishments in one calendar year, efforts are made to ensure that the information and knowledge gained from the inspections are of use to the whole healthcare system.

Risk-based inspections as of 2017 has the following priority areas and themes[25] :

- In 2017, supervision of medication management and patient progress monitoring responses with a focus on patients with depression and patients with COPD;
- In 2018, supervision of drugs and stages in the progress of patients treated with them, with a primary focus on patients with schizophrenia and concurrent somatic illness, as well as patients with chronic illness and comorbidities (diabetes);
- In 2019, supervision of diagnosis and treatment, with a focus on surgical activities.

The Patient Safety Agency is responsible for supervision of all types of healthcare services. Inspections can be planned and occasional[26]. Planned inspections are normally anounced six weeks before they are due to take place. A notification letter is prepared for this purpose, describing what will be audited and who will attend. Incident audits may result from a notice, complaint, transcript, etc. It is characteristic of this type of initiation of inspection that the whistleblower is protected from subsequent sanctions and/or consequences. An incident control may be conducted with or without notice to the person or facility being inspected. This scrutiny implies active monitoring in the form of an inspection or other agency review. In cases where the agency has information or evidence that circumstances exist that pose a hazard or a reasonable potential risk to patient safety, it must take appropriate action to ensure patient safety.

[25] https://stps.dk/da/sundhedsprofessionelle-og-myndigheder/det-risikobaserede-tilsyn/temaer-og-maalepunkter/forslag-til-temaer-og-omraader/

[26] Styrelsen for Patientsikkerhed, Strategi for tilsyn Styrelsen for Patientsikkerhed, December 2017, https://stps.dk/da/udgivelser/2017/strategi-for-tilsyn/~/media/107551FC9BF54B68920F712FCA9440B2.ashx

As a result of the inspection, and if deemed appropriate, the Agency may make prescriptions and/or orders to the person or establishment inspected, and, if necessary, require temporary or partial suspension of the activity.

The indicators the DPSA works with are selected based on a risk analysis. As a result of the overall assessment of the occurrence of a particular or recurrent risk to patients, the selection of indicators is made, with the overall assessment of the occurrence of a particular risk being derived from the database maintained by the agency. A Follow-up Board has also been established within the Agency to assist in the selection of themes and the choice of indicators and their evaluation.

3.3.4. PORTUGAL

ERS[27] is the abbreviation of the Portuguese Health Control Agency. It is an independent public body that oversees the activities of healthcare providers in Portugal. The scope of its control powers includes all healthcare providers located in the territory of Portugal, of a public, private or social nature, whether individual or collective organisations. The ERS oversees the activities of 15 000 healthcare providers.

The main ERS functions include:

- ✓ Monitoring compliance with regulatory requirements related to the provision of health services and healthcare establishments;
- ✓ Protecting patients' rights, including access to services and freedom of choice;
- ✓ Monitoring the legality and transparency of economic relations between suppliers, consumers and financing institutions;
- ✓ Monitoring the healthcare market for unfair competition.

The activities that ERS carries out are:

- ✓ Registration of healthcare providers;
- ✓ Complaint and whistleblowing investigations of patients, providers and institutions;
- ✓ Inspections and audits of the activities of healthcare providers;
- ✓ Investigation of cases with a significant adverse impact on patients' rights or the quality and safety of healthcare services;
- ✓ Implementation of administrative proceedings and imposition of administrative penalties on healthcare providers;

[27] Entidade Reguladora da Saúde https://www.ers.pt

✓ Performing inspections (including thematic inspections), issuing instructions and recommendations.

For the purpose of its control activities, the Agency performs the following types of controls:

✓ Scheduled (periodic) inspections - mainly inspections for compliance with regulations, quality and safety requirements of healthcare facilities, including minimum technical requirements for users, documentation, organization and operation, electrical installations, medical gases, mechanical equipment, etc.

✓ Inspections when applying for an activity permit.

✓ Thematic inspections - for the purpose of monitoring common processes, at the request of third parties, complaints from patients or at the request of inter-institutional cooperation.

The teams performing the inspections are multidisciplinary and normally consist of a lawyer, a medical specialist and an engineer, and may be supported by experts in certain specialties, depending on the complexity of the inspection and the scope of the institution being inspected.

In 2009, an electronic system (SINAS) was introduced in Portugal to evaluate hospital care facilities in terms of quality assurance and patient safety. Participation in the evaluation system started as voluntary, but at the end of 2017, ERS reported that 79% of hospitals in Portugal participate in the system. Access to this information is considered to be the consumer's fundamental right. The publication of evaluation results ensures access to adequate and comprehensible information, thus encouraging healthcare users to make more informed decisions and, on the other hand, it is a means of continuous improvement of the quality of service by healthcare providers. In this way, a kind of rating of healthcare establishments is developed.

Hospital facilities perform a self-assessment once a year and submit the information to the system. ERS carries out checks before validating the information submitted and, based on the results, plans its control activities for the following year, issuing recommendations or guidance in areas where weaknesses have been identified.

The development of the system and all its methodology is with the assistance of JCI (Joint Commission International), and based on a broad public consensus. Another important feature of the system is the public availability of the results of the hospital evaluation and the continuous on-line access to them for all users of health services.

Hospitals are evaluated in two stages. The first stage is related to confirming the fulfilment of criteria that ERS considers important for the provision of quality services. In this stage, indicators in the area of the structure and organisational culture of the hospital are considered. In the second stage, each hospital receives an individual rating that makes it possible to compare it with other hospitals. There are three levels - a top level, an intermediate level and a base level.

The indicators used for evaluation purposes are performance (achievement) indicators. They may be individual or based on an analysis of sub-indicators (aggregated). Indicators are classified using the standard typology of structure, process and outcome. All indicators included in the model are selected to cover the following characteristics:

- ✓ Valid - give a true representation of the quality in the area being assessed;
- ✓ Accepted - to be recognised as important;
- ✓ Sensitivity - make it possible to detect acceptable differences in the quality of the health service;
- ✓ Realistic - must be applicable to everyday clinical practice.

Sinas - National Health Service Evaluation System

A scientific and technical approach is embedded in all aspects of the system, with the principles of rigor, transparency and objectivity at its core. The approach used best promotes the realisation of the legal rights of patients and all the subjects and entities involved in the health insurance system.

Various indicators are used in the evaluation of healthcare facilities, which depend on the type and profile of healthcare provided. At present, a module for hospitals (Sinas @ Hospitals) has been developed and implemented, and all the criteria developed are tailored to the type and profile of the medical specialty, followed by a module for dental service providers (SINAS@Saúde.Oral).

Controls are implemented by ERS through periodic audits of healthcare providers that are randomly selected to validate submitted information.

The supplier evaluation process is carried out at two levels. During the first level of rating, the SINAS module allows for the validation of compliance criteria, which ERS believes are essential for the provision of quality health care by analyzing multiple and varied indicators. Upon validation at this level, the competent authority awards one star, allowing the healthcare facility to

move on to the second level of assessment. The second level aims to give an objective rating of the healthcare establishments, which will enable comparative analysis through indicators. At this level, quality parameters are assessed, which are set in three levels:

Quality level III - the highest category;

Quality level II - intermediate level;

Quality level I - basic level.

By their very nature, the performance quality indicators analysed by the SINAS module can be attributed to the classic Donabedian model: **structure, process and outcome**, which in turn points towards the definition of evidence-based **medicine.**

The Sinas module also evaluates the "Satisfaction Indicators". In these cases, the users of the healthcare services evaluate the quality according to their subjective perceptions.

3.3.5. ESTONIA

The population of Estonia is 1 315 000 inhabitants, of which 1 200 000 or 92% are insured. The population is unevenly dispersed, with a clear tendency towards urbanisation, which was also taken into account when drawing up the Estonian master plan, adopted on 17 April 2000. Estonia has only one state health insurance fund (EHIF), which has contracts with all 19 state hospitals.

In order to ensure the quality of the healthcare services provided, quality requirements for healthcare were established in 2002 and a system for monitoring and control of the activities of healthcare providers was set up.

The evaluation and resolution of health service quality issues are performed by[28] :

1. The healthcare provider within its internal quality management system. The service provider shall ensure the quality of its organisation and management, the professional quality of patient care and the medical care provided and assess patient satisfaction.

It is stipulated (Ordinance No. 128 of the Minister of Social Affairs of 15 December 2004 "Requirements for Quality Assurance of Health Services"[29]) that the health service provider is responsible for the quality of the services provided to the patient. **The healthcare facility is**

[28] https://www.haigekassa.ee/tervishoiuteenuste-kvaliteet-ja-jarelvalve, accessed 27.08.2022.
[29] https://www.riigiteataja.ee/akt/828314?leiaKehtiv, accessed 27.08.2022.

obliged to develop and implement a quality management system in order to ensure and develop the quality of health services and reduce the risks associated with their provision.

To ensure patient satisfaction and manage the risk associated with the provision of healthcare services, the healthcare provider must:

-- develop patient satisfaction analysis and assessment criteria that ensure patient satisfaction and enable management of risks associated with the provision of healthcare services;

-- to develop and inform patients of the provider's standard of care;

-- to prominently display the patient's right to appeal the actions of healthcare workers to the director of the healthcare facility, the Estonian Health Insurance Fund or the Health Board;

-- to summarize, analyze and discuss patient satisfaction and complaints at least annually. The results of the patient satisfaction analysis shall be made public at the healthcare provider's place of business and on the healthcare provider's website.

In order to assess the quality of the healthcare service and reduce risks, the healthcare provider must:

-- to record transfusion reactions occurring during the provision of the healthcare service;

-- to request an opinion from the Advisory Expert Committee on the Quality of healthcare services in disputed cases of healthcare services;

-- to use clinical audit, self-assessment, control of treatment documents;

-- to record adverse reactions arising from the use of medicines and inform the Drug Agency about them;

-- to organise regular in-hospital clinical conferences, with the participation of relevant specialists and general practitioners where appropriate;

-- to establish the arrangements for the conduct of specialist advice in the provision of hospital care.

To ensure the quality of the healthcare service, the specialised care contractor shall establish operational guidelines:

-- for the control and prevention of nosocomial infections;

-- for prescribing medicines, including antibiotics, together with the hospital prescription form;

-- to prevent and treat bedsores;

-- to arrange transfusion therapy;

-- to assess the preoperative condition of a patient;

-- for the use of radiation in diagnostic and therapeutic procedures.

The obligations of healthcare providers regarding the accessibility of the healthcare service provided and the maintenance of a waiting list are established (Regulation No. 46 of the Minister of Social Affairs of 21 August 2008 "Requirements for the provision of health services and maintenance of waiting lists for treatment"[30]). Healthcare services may be provided on the basis of a waiting list in the event that the healthcare provider is unable to provide the service immediately and delaying it until a certain time does not lead to a deterioration in the patient's health condition, does not affect the course of the disease and does not worsen the later prognosis of the disease.

2. EHIF for quality assurance

Under the Estonian Health Insurance Fund Act, the EHIF is obliged to monitor the quality of healthcare services and determine whether their provision is justified. The means of monitoring are:

- monitoring the overall health insurance picture;
- clinical audits;
- methods for measuring activities and results;
- DRG-s /diagnostic related groups/.

In order to improve the quality of health services, EHIF also supports the activities of a number of professional associations and medical institutions in areas such as:

- improving the quality of data provided in the course of reporting;
- support and launch various development projects to explore international best practices.

The main objectives of the EHIF are:

- ✓ Institution organising national health insurance;
- ✓ EHIF is the only organisation in Estonia that deals with compulsory health insurance;

The purpose of the activities is:

- ✓ compensation for healthcare costs;
- ✓ financing the purchase of medicines and medical equipment;

[30] https://www.riigiteataja.ee/akt/129122018018, accessed 27.08.2022.

- ✓ payment for various benefits.

The EHIF has over 1.2 million clients - compulsorily insured persons.

To achieve its objectives, the EHIF shall:

- ✓ arrange health insurance;
- ✓ ensures the effective and efficient use of funds;
- ✓ control the quality, volume and justification of the services paid for by the Fund.

In Estonia, the commitment and authority to control the quality of medical care by the state is the responsibility of the EHIF. This is possible as all hospitals are under the control and management of the state.

EHIF has established a Guidelines Advisory Board to improve the quality of healthcare services provided to patients by leading the process of developing cost-effective and medically evidence-based Estonian treatment guidelines that take into account local conditions.

A clinical guideline is a document that makes recommendations for actions that affect health. It provides healthcare professionals with evidence-based guidance on different methods of diagnosis and treatment and may also contain recommendations for both disease prevention strategies and patient education. The information provided in clinical guidelines helps to make choices between different intervention methods, taking into account their impact on health, quality of care and use of health resources.

The initiative to develop clinical guidelines can come from any organization (e.g., professional association, patient group, educational institution, etc.). All clinical guidelines adopted by the Advisory Board (a dedicated structure set up within the EHIF) can be found on the institution's website and are accessible to all patients.

3. The Health Board is a state institution subordinate to the Ministry of Social Affairs, which exercises state supervision and applies state coercion on the grounds and to the extent determined by law.

The Health Board’s areas of activity are health, infectious disease monitoring and epidemic control, environmental health, chemical safety and medical device safety. The purpose of the Health Board is to implement policies aimed at shaping a health-sustaining and health-enhancing living and learning environment in these areas.

The healthcare provider must apply for a license to operate from the Health Board. The Health Board's Oversight Division inspects all healthcare service providers and assesses how well their activities meet regulatory requirements.

4. The role of the **Advisory Expert Committee** (a structure of the Estonian Ministry of Social Affairs, whose remit includes the health sector) is quality assurance.

In cases where there is doubt about the quality of the medical services provided (medical appropriateness), it is recommended that the persons concerned refer to the Advisory Expert Committee on the Quality of Health Services, working under the Ministry of Social Affairs. The Advisory Expert Committee on Quality of Health Services is an advisory committee whose purpose is to evaluate the quality of healthcare services provided to the patient and make recommendations to the EHB, EHIF and the health care provider based on this evaluation. The Committee's jurisdiction is only engaged in cases of high complexity. Its members are generally designated to be habilitated individuals who are of retirement age and who have no direct interest or employment relationship with healthcare providers. This assumes that they are impartial and equidistant from the subjects involved.

It is within the competence of the Commission:

1) assess the quality of services provided to patients in terms of medical appropriateness;

2) to make proposals to the EHIF for monitoring the performance of the medical service provider;

3) suggest that the medical provider assess the professional competencies of the staff and recommend further training for the staff;

4) to instruct medical service providers to change the organisation of their work;

5) make proposals to the EHB for the revocation of a medical service provider's operating licence;

6) make proposals to the EHB for refusal of a licence to operate as a medical service provider;

7) make proposals to the EHIF for the imposition of financial corrections on a contracted medical service provider.

3.3.6 SWEDEN

In 2010, oversight of social services was transferred to the National Health and Social Care Board and in 2013 the National Health and Social Care Inspectorate IVO was established to create a more effective, robust and leaner oversight organisation. As of June 1, 2013, IVO is responsible for supervision of healthcare, social services and activities in accordance with current legislation, as well as issuing permits for certain activities. The IVO is a government agency under the Ministry of Health and Social Care. The annual budget of the Inspectorate is around EUR 70 million, with a staff of 730 employees, of whom around 400 are inspectors.

IVO inspects about 40,000 service providers, such as but not limited to:

- 1 200 healthcare centres;
- 90 hospitals;
- public dental services (about 1,000 clinics and about 1,250 private dental clinics);
- 1 000 nursing homes;
- 2 000 elderly homes;
- 1 300 pharmacies;
- 7 600 dentists;
- 40 000 doctors;
- Over 100 000 nurses.

The main activities of the Inspectorate include:

- Obligations to produce reports and provide information on the status of services;
- Complaint handling;
- Perform risk-based supervision;
- Carry out supervision assigned by the government;
- Supervision of the activities of medical professionals;
- Taking action against service providers and staff (warrants, reporting to the Public Prosecutor's Office, prohibition of activity or withdrawal of authorisation).

Risk-based supervision, which IVO carries out by producing risk analyses. Supervision is focused on services that are identified as particularly important. The aim is to identify risks in

health and social care services. The analyses are based on observations from inspections carried out by IVO and from external sources of public interest.

Supervision contributes to the provision of safe and high quality health and social care and works to provide the best service to its recipients.

Supervision focuses on the user and patient perspective and on issues that are important to individuals or groups. Unless laws or regulations provide otherwise, supervision should be risk-based and address only issues that are essential to providing a safe and high quality health and social care service.

In order to meet the requirements of the Public Management Agency, the principle of "trust-based public management" has been introduced in IVO. Applying the principle of trust-based management is part of the Government's reform agenda in all public areas: 'Management must draw on the skills of its employees to bring benefits to citizens and businesses. This is the starting point of the reform agenda, through trust-based governance". The key question that is being asked is how supervision can contribute more to quality improvement and training. Trust-based management is a culture of work and working procedures focused on the objectives of organisations and the needs of users.

The key to moving from complaint-based to improvement-based supervision is to organise supervision in such a way that quality improvement activities are not hindered, but on the contrary that each inspection contributes to quality improvement. The key to achieving this is not only what is found, but an analysis of the reasons that led to the particular action or decision.

3.3.7. FRANCE

Health care provision in France is a national responsibility. The Ministry of Social Affairs, Health and Women's Rights is responsible for defining the national health strategy. It defines and implements public health policy and the organisation and financing of the health system. Over the last two decades, the State has become increasingly involved in controlling health expenditure financed by the National Union of Insurance Funds[31] by regulating approximately 75 percent of health expenditure based on the general framework established by Parliament. The government allocates budget expenditure between different sectors - hospitals, ambulatory care, mental health and disability services on the one hand and regions on the other. The regional health agencies (Agences Régionales de Santé/ARS), as the Ministry's representatives in the regions, are

[31] O. Nay et al, "Achieving Universal Health Coverage in France: Policy Reforms and the Challenge of Inequalities," *Lancet* 387, no. 10034 (May 28, 2016): 2236-49.

responsible for coordinating population health and health care, including prevention and care delivery, public health and social care.

In France, the safety and quality of healthcare is mainly guaranteed by:

1. A set of regulatory measures that apply to operations and activities in different areas: authorizations to practice or set up equipment, organization of public and private healthcare facilities, technical conditions of operation in high-risk sectors, monitoring the use of health products, etc.;
2. Several sector-specific monitoring programs that are used to detect adverse effects related to the use of health products as well as related to the treatment of adverse incidents and events;
3. Regulatory authorities have organised region by region so that inspections and compliance checks can be carried out on the spot;
4. Certification system for healthcare facilities;
5. Best practice recommendations for health professionals, drawn up by the national authorities (Haute Autorité de Santé/HAS, Haut Conseil de Santé Publique) and approved by the health authorities;
6. State-approved/recognized health professions licensure programs.

Programs have also been established to ensure compliance with healthcare quality and safety standards and prerogatives.

Mechanisms used to identify non-compliance with established quality and safety standards of care:

1. The French ARS register any complaints and signals submitted by patients and their families, professionals and members of the public, and carry out on-site inspections whenever they deem it necessary.
2. Specific risks related to health products, medical use of ionising radiation, infections associated with the care provided and assisted reproduction are dealt with by specialist agencies.
3. There is currently a system in place (in the process of being implemented) that can be used to identify healthcare facilities and to authenticate healthcare professionals who are authorised to practice. The professional bodies, together with the regional health agencies, are closely involved in the implementation of the approval and updating mechanism and publish a list of health professionals who are authorised to practice.

To promote improvements in the quality and safety of care and to meet the demands of patients and users, the Department of Health is implementing a policy of transparency. All healthcare facilities are required to publish their performance to the public.

Along with the above, the indicators are used in the certification of healthcare facilities by HAS and for financial incentives for quality improvement.

Since 2008, HAS has been conducting national campaigns to collect indicators/indicators of quality and safety of healthcare in all healthcare facilities. The indicators are used in different systems at national and regional level, such as the Financial Incentive System for Quality Improvement (IFAQ), multi-year contract for health facilities' goals and funds, certification of healthcare facilities, etc. These indicators are also used in the implementation and monitoring of public health plans for the prevention of infections related to indicated care, psychiatry and mental health, stroke, obesity, cancer and pain[32] .

The inspection is carried out within the framework of the National Inspection Guidelines (ONIC) of the Inspectorate General for Social Affairs (IGAS). The main focus of inspection is in relation to those healthcare facilities where a significant over-performance is noted in one or more of the indicators, with the aim of achieving a higher level of performance. In these cases, the results of the ARS control activity are of utmost importance, which have the effect of confirming/validating or rejecting the information collected from the indicators.

If validation is denied, the facility's results cannot be used in existing national and regional systems, and a "not validated" notation is displayed on the public information website for quality and safety of care in hospitals and clinics, www.scopesante.fr, until the next collection of indicators.

When the ARS control score is consistent with that of the health facility, the indicators are validated and the health facility's score is displayed on the Scope santé. In these cases, the results can be used in national and regional systems.

To prevent risks, agencies carry out inspection and control in three areas: health security, operation of facilities and services, medical acts and practices of professionals.

Regional Health Agencies (ARS) were established in 2010. They are responsible for the regional management of the health system. They are the body that defines and implements regional

[32] https://www.has-sante.fr/jcms/c_2037372/en/controle-qualite-du-recueil-des-indicateurs-nationaux

health policies in the region. The aim is to respond as best as possible to the needs of the population. They are independent, financially autonomous public bodies placed under the supervision of the ministries responsible for social affairs and health.

The activity carried out by the agencies has two dimensions, territorial and economical. In the former, the activity is aimed at a better distribution of medical professionals and supply of care within the region, and in the latter, at a better use of resources and control of healthcare costs.

Control by ARS

In planning their control activities, the agencies are guided by national guidelines and regional planning.

Agencies carry out three main types of inspections:

1. Those identified by the National Annual Programme from the National Commission for Planning Inspection and Control;
2. Defined in the annual regional control programmes;
3. Sudden/Incidental Checks.

In 2015, regional health agencies conducted over 25,000 inspections[33] .

Each year, the National Commission for Planning Inspection Control (CNPIC) prioritizes inspection topics (National Inspection Control Guidelines). Each agency, in preparing the regional inspection plan, takes into account the overall national guidelines and the priorities defined for the region.

4. COMPARATIVE ANALYSIS

4.1. MODELS OF CONTROL APPLIED BY EUROPEAN SUPERVISORY ORGANISATIONS

European countries face common problems in the area of healthcare supervision. Most often they are organisational, problems related to shortages of staff, equipment or finances, which have a negative impact on the quality of healthcare services provided. There is also a shared perception that healthcare supervision should contribute to solving problems, be focused on assessing performance rather than being a tool for assessing the level of compliance with formal regulations and standards, and for imposing sanctions. Supervision should encourage proactive

[33] https://www.ars.sante.fr/la-mission-dinspection-controle-des-agences-regionales-de-sante?parent=4620

action by those carrying it out, which is why countries are increasingly changing their approaches to control towards risk-based control, believing that this will provide a real and effective assessment of the quality of the performance of health care establishments. The point of this approach is that healthcare supervisory organisations and health care providers identify, assess and understand the risks associated with the safety and quality of healthcare services.

There are three main models of risk-based supervision[34] . The leading difference between the three models relates to the way the data is collected.

1. Control based on proactive risk analysis[35]

Proactive risk analysis is at the heart of the model. It is aimed at identifying high-risk areas for future supervision activities. The analysis is based on data from supervisory information databases and external sources. Based on a comprehensive assessment of the occurrence of particular and recurrent risks to patients, especially the most vulnerable, risk-based supervision topics are identified.

This model includes:

- studying the healthcare delivery system to identify factors that could potentially lead to harm to patients during treatment, with
- developing and taking action to prevent future recurrence.

The purpose of the model is to establish a baseline risk profile for each type of healthcare facility. It is considered that it will help to identify high-risk areas for future supervision activities using other sources of risk analysis. This type of supervision is applicable to all types of establishments, the selection being based on an assessment of the highest risk to patient safety. Successful implementation of the approach allows for an efficient use of the resources of the supervisory organisation and is a key strategic criterion for its successful activity. In this approach, the proactive risk analysis used is based on an examination of available data from patient safety adverse event reporting systems, complaints, surveys, advisory body opinions and other sources. Stakeholders are invited to actively participate in the identification of priority areas for supervision, thereby aiming to ensure clinical relevance and legitimacy.

The risk assessment allows to identify the risk areas and the topics of the planned supervision. The proactive risk analysis as well as the identified priorities allow the development

[34] Petrova Zl., T. Cherkezov, R. Zlatanova-Velikova, E. Petrova-Jeretto Ph.D., Al. Gigova. "Risk-based controls in health care, ed. Bivalvia Ltd" 2020, ISBN:978-619-91569-0-2, p.204
[35] Petrova Zl., T. Cherkezov, R. Zlatanova-Velikova, E. Petrova-Jeretto Ph.D., Al. Gigova. "Risk-based controls in health care, ed. Bivalvia Ltd" 2020, ISBN:978-619-91569-0-2, p.204

of verification indicators that are public and ensure that the healthcare facilities maintain the highest possible level of patient safety. These indicators are the basis for assessing the risk profile of healthcare establishments. In order to increase the efficiency of supervision and to focus on knowledge sharing rather than necessarily on the imposition of sanctions in relation to supervision, the establishments to be inspected are notified in advance.

2. Risk-based control through a national healthcare service evaluation system[36]

The need for a blended approach to assessing the safety and quality of health care is at the heart of the model, which aims to assess health care providers on multiple dimensions of quality. The model uses data from national healthcare service evaluation systems. This allows for the assessment of various quality indicators of healthcare providers using objective and evidence-based criteria, including patient satisfaction levels.

Different indicators are used and evaluated for the assessment of different profile healthcare establishments, and by their nature, performance quality indicators can be classified within the classic Donabedian type of model: structure, process and outcome. A characteristic of this method is that the collection of data requires the cooperation of health care providers, whose activity in the process and personal participation guarantee the veracity of the information provided. The data collected are evaluated by applying specially developed methodologies in order to achieve, as a final result, an objective ranking of each healthcare establishment. Supervisions are carried out by the supervisory authority through periodic audits of healthcare providers selected at random in order to confirm the information provided.

By its very nature, this is also a way of developing a kind of rating of healthcare providers. The publicity of the data provides adequate information that facilitates and encourages patients to make more informed decisions and, on the other hand, helps to continuously improve the quality of healthcare.

One of the main advantages of this model is the integration of risk assessment and risk management processes with continuous quality improvement processes in a logical whole, with the active and conscious participation of the healthcare establishments.

[36] Petrova Zl., T. Cherkezov, R. Zlatanova-Velikova, E. Petrova-Jeretto Ph.D., Al. Gigova. "Risk-based controls in health care, ed. Bivalvia Ltd" 2020, ISBN:978-619-91569-0-2, p.204

3. Control based on risk assessment through analysis of data collected in the course of supervisions[37]

The model is used to plan the supervisory authority's control activities using an evidence-based risk assessment method and analysis of data accumulated in the process of monitoring and regulating registered healthcare services. An advantage of the model is the use of data collected in the course of inspections, which allows a clearer and more objective picture of the safety and quality of healthcare services to be built up than standard health statistics. On the other hand, it provides an opportunity to select data that are most informative for the needs of a particular supervision. For the successful implementation of the model, data from supervision activities carried out on no less than half of the inspected facilities are collected. The selected quality indicators are monitored by a computational model that estimates the level of risk for each facility. The computational model is developed on the basis of the identified and collected 'control-relevant' data. Once the model is in place, planned supervision focuses on areas where the model indicates high risk or a need for quality improvement actions. On the other hand, all new services remain subject to mandatory planned supervision.

The advantage of applying this method is the better organization of supervision activities, as well as the opportunity to build a common understanding of the quality of healthcare services. The method facilitates the implementation of good practices, while at the same time drawing the attention of supervisors to poor quality services where the most timely action should be taken.
Last but not least, it ensures that the resources of the supervisory authority can be used as efficiently as possible without burdening the healthcare establishments with additional obligations.

4.2. COMPARATIVE ANALYSIS OF THE RESEARCHED SUPERVISORY ORGANISATIONS

For the purpose of comparison and comparability of the different supervisory organizations, the subject of the study, a comparative analysis was made, which is based on the following indicators - name and type of supervisory organization, areas in which supervision/control is carried out, objects/entities subject to supervision/control, model of supervision/control, form of patient involvment in supervision/control activities, benefits of supervision/control activities, risks of supervision/control activities, consequences of

[37] Petrova Zl., T. Cherkezov, R. Zlatanova-Velikova, E. Petrova-Jeretto Ph.D., Al. Gigova. "Risk-based controls in health care, ed. Bivalvia Ltd" 2020, ISBN:978-619-91569-0-2, p.204

supervision/control activities. Some of the indicators have been borrowed from "Risk-based controls in healthcare"[38] .

Table 1 Comparative analysis - Part 1

	England	**Finland**	**Denmark**
Name and type of supervisory authority	Care Quality Commission (CQC)	VALVIRA - the National Control Body for Wellbeing and Health was set up within the Ministry of Social Care and Health. AVI regional state administration	DPSA is the Danish Patient Safety Authority
Areas of supervision/control	The CQC scrutinises the activities of health and social care providers in England.	VALVIRA is responsible for supervision of social and health care, and also supervision under the Alcoholic Beverages and Public Health Protection Act. AVI are the main supervisors at regional level. The main supervision is related to patients' complaints about healthcare services.	The DPSA controls the activities of health care providers (medical professionals and healthcare establishments)
Objects/entities subject to supervision/control	All healthcare establishments (inpatient and outpatient) as well as individual practices. All social care facilities.	Registered social care professionals and registered social care organisations, registered healthcare professionals and registered	The activities of general practitioners and healthcare establishments, as well as the activities of social care establishments

[38] Risk-based controls in healthcare, Prof. Dr. Zl. Petrova, PhD, prof. Dr. Todor Cherkezov, D. M., prof. Dr. Ralitsa Zlatanova - Velikova, Ph.D., Elisaveta Petrova - Djereto, Ph.D., Alexandrina Gigova, Sofia, 2020.

		healthcare establishments	
Supervision/control model	The Commission performs risk-based control by analysing data collected in the course of the inspections carried out	VALVIRA performs control based on proactive risk analysis	DPSA performs control based on proactive risk analysis
Form of patient involvement in supervision/control activities	• The Commission works closely with patient organisations • Provides patient information and education • Use of feedback (surveys, etc.) as an element in risk assessment • Use of so-called "experts by experience" in control activities	• The main way for patients to participate in the system of control of healthcare facilities and health professionals is through the established system of complaints and signals. • Conduct national surveys every 2 years	• The Agency works closely with patient organisations • Patient involvement in the development of guidelines and indicators used by the Agency
Benefits of supervisory/control activities	• Efficient use of capacity and resources • Targeting of control activities at the places with the highest probable risk • Use of objective and verified data collected in the course of ongoing inspections for risk assessment • Establish baselines for acceptable risk, taking into account the objective state of the system • Motivating healthcare facilities to improve quality and related indicators of their performance • Using the control results to "learn" the system	• Efficient use of capacity and resources • Targeting control activities to areas of greatest likely risk • Proactive approach to risk assessment based on preliminary information from different sources • Establishment of indicators and benchmarks to ensure the highest level of safety • Motivating controled facilities to self-assess and prevent risks	• Efficient use of capacity and resources • Targeting control activities to areas of greatest likely risk • Proactive approach to risk assessment based on preliminary information from different sources • Establishment of indicators and benchmarks to ensure the highest level of safety • Motivating controled facilities to self-assess and prevent risks

		• Using the control results to "learn" the system	• Using the control results to "learn" the system
Risks of supervisory/control activities	Delays in the process of collecting initial risk assessment data due to lack of capacity to cover a sufficient number of control facilities.	• Use of information from external sources whose objectivity and reliability cannot be sufficiently guaranteed at the planning stage • Focusing risk assessment on specific areas and control topics rather than specific control facilities in the absence of sufficient capacity can lead to gaps associated with establishments of particular risk	• Use of information from external sources whose objectivity and reliability cannot be sufficiently guaranteed at the planning stage • Focusing risk assessment on specific areas and control topics rather than specific control facilities in the absence of sufficient capacity can lead to gaps associated with establishments of particular risk
Consequences of supervisory/control activities	• Restriction of services provided by the establishments • Suspension (closure) of services provided • Administrative penalties • Initiation of criminal prosecution	VALVIRA issues instructions, recommendations and advice to the controlled facilities. Active work is being done to introduce so-called "interactive supervision", which shifts the focus of control from sanctioning and punishing to promoting dialogue and cooperation through meetings, discussions, information sharing and feedback.	• The Agency may issue prescriptions and injunctions which shall be mandatory • If necessary, may require temporary or partial suspension of the healthcare provider's activity.

Table 1 Comparative analysis - Part 2

	Portugal	**Estonia**	**Sweden**
Name and type of supervisory authority	ERS is Portugal's healthcare supervisory agency	1. EHIF - Estonian Health Insurance Fund; 2. Advisory Expert Committee on the Quality of Healthcare Services at the Ministry of Social Affairs and 3. Health Board of the Ministry of Social Affairs	National Inspectorate for Health and Social Care (IVO)
Areas of supervision/control	ERS controls the activities of all healthcare establishments located in Portugal	EHIF verifies the validity and quality of the healthcare services provided by the contractual partners. The Health Board inspects all healthcare providers to see if they meet the requirements set by legislation (formal verification). The Advisory Expert Committee assesses the quality of healthcare services (medical appropriateness) provided to the patient	The IVO controls the activities of healthcare providers (medical professionals and healthcare facilities) as well as social care providers

Objects/entities subject to supervision/control	All healthcare establishments (inpatient and outpatient) regardless of ownership, as well as individual practices	Healthcare establishments, individual practices	The activities of general practitioners and healthcare establishments, as well as the activities of social care establishments
Supervision/control model	ERS carries out risk-based control through a national health service rating system	Control based on risk assessment through a national health service assessment system	IVO performs risk-based control by analysing data collected in the course of the inspections carried out
Form of patient involvement in supervision/control activities	• Works in collaboration with patient organisations • Use of feedback (surveys, etc.)	• Works in collaboration with patient organisations • Use of feedback (surveys, etc.)	• IVO has practices to interview consumers, patients and their relatives • Work closely with patient organisations • Patient participation in the development of guidelines and indicators used by the Agency
Benefits of supervisory/control activities	• Efficient use of capacity and resources • Targeting of control activities at the facilities with the highest probable risk • Opportunity for healthcare facilities to self-assess and benchmark their performance • Motivating healthcare facilities to improve quality and related indicators of their performance • Using the control results to "learn" the system	• Efficient use of capacity and resources • Targeting of control activities at the facilities with the highest probable risk • Opportunity for healthcare facilities to self-assess and benchmark their performance • Motivating health facilities to improve quality and related	• Efficient use of capacity and resources • Targeting of control activities at the facilities with the highest probable risk • Using objective and verified data collected in the course of ongoing inspections for risk assessment; • Establish baselines for acceptable risk, taking into

		indicators of their performance • Using the control results to "learn" the system	account the objective state of the system. • Motivating healthcare facilities to improve quality and related indicators of their performance; • Using the results of "learning" controls in the system
Risks of supervisory/control activities	• Healthcare establishments not sufficiently motivated to participate in the national quality assessment system • The data entered into the system by the healthcare facilities are not reliable and lead to deviations in the quality and risk assessments	• Healthcare establishments not sufficiently motivated to participate in the national quality assessment system • The data entered into the system by the health care facilities are not reliable and lead to deviations in the quality and risk assessments	• Delays in the process of collecting initial risk assessment data due to lack of capacity to cover a sufficient number of control facilities.
Consequences of supervisory/control activities	• Implements administrative proceedings • Imposes administrative penalties on healthcare providers • Issue instructions and recommendations	EHIF review of the contractual relationship with the healthcare provider. The Advisory Expert Committee on Quality makes proposals of different nature. If a medical error is detected, it notifies the physician and the healthcare institution that made the error and, if necessary, proposes that the professional association verify	• IVO issues orders • report to the prosecution • may prohibit an activity • May withdraw permission

		the competence of the physician who made the error. In its decision, the committee may make suggestions, give advice or make recommendations, but may not oblige the doctor or the establishment to compensate the patient for the damage caused by the medical error. The Health Board may reconsider the authorization to practice granted.	

Table 2 Comparative analysis - Part 3

	France	**Bulgaria by 2019**	**Bulgaria after 2019**
Name and type of supervisory authority	Regional Health Agencies (RHAs). They are the Ministry's representatives in the regions and are responsible for coordinating population health and healthcare, including prevention and care delivery, public health and social care	Executive Agency "Medical Audit"	Executive Agency "Medical Supervision"
Areas of supervision/control	The ARS inspects the activities of all health care providers located within the territory of the agency.	EAMA inspects all healthcare establishments, including individual medical specialists	The powers of the EAMS compared to those of EAMA are significantly expanded, but the scope of the control activity is identical to that of EAMA
Objects/entities subject to supervision/control	All healthcare establishments (inpatient and outpatient) regardless of ownership, as well as individual practices	All healthcare establishment - inpatient and outpatient care	EAMS controls the same entities as EAMA

Supervision/control model	ERS provides risk-based control through a national health service rating system	EAMA provides control based on risk assessment through analysis of data collected in the course of the inspections carried out. Thematic inspections of resource-intensive and high-risk activities - drugs, oncology, invasive cardiology, etc.	The EAMS does not apply any of the three models of supervision and does not provide risk-based control
Form of patient involvement in supervision/control activities	• Cooperation with patient organisations • Use of feedback (surveys, etc.) • Use of so-called "experts by experience"	• Use of feedback (surveys, etc.) • Receiving complaints from patients	• Receiving complaints from patients
Benefits of supervisory/control activities	• Efficient use of capacity and resources • Targeting of control activities at the facilities with the highest probable risk • Opportunity for healthcare facilities to self-assess and benchmark their performance • Motivating healthcare facilities to improve quality and related indicators of their performance • Using the control results to "learn" the system	• Efficient use of capacity and resources • Targeting of control activities at the facilities with the highest probable risk • Using objective and verified data collected in the course of ongoing inspections for risk assessment; • Establish baselines for acceptable risk, taking into account the objective state of the system. • Motivating healthcare facilities to improve quality and related	Not identified

		indicators for their activities; Using the control results to "learn" the system	
Risks of supervisory/control activities	• Healthcare establishments not sufficiently motivated to participate in the national quality assessment system • The data entered into the system by the healthcare facilities are not reliable and lead to deviations in the quality and risk assessments	• Delays in the process of collecting initial risk assessment data due to lack of capacity to cover a sufficient number of control establishments.	The Agency's failure to apply a risk-based approach to control leads to an excessive workload for its staff. On the other hand, instead of proactive control, the Authority mainly carries out ex-post control.
Consequences of supervisory/control activities	The results of the control are intended to confirm/validate or reject the information collected from the indicators to achieve a higher level of performance of the activities	Making recommendations, issuing penal orders, using the collected database to perform system analysis	Issuing mandatory prescriptions and/or issuing penalty notices to the offender

A comparison of practices in the countries studied confirms the thesis that governments are under pressure to do more with less due to ever-increasing costs. Countries are striving to strike a balance between health system costs and the quality of healthcare services. In order to reduce costs in the system, many are changing their systems, which in some cases are too complex. Many governments in Europe are under pressure from public opinion on the quality and safety of healthcare, and there is an imbalance between the expectations of the population and what they receive. Next, a significant imbalance between efficiency and costs in some countries is also creating a growing number of inpatient healthcare facilities.

The supervisory authorities examined are actively developing mechanisms to conduct risk-based control. One reason is that risk-based control provides an opportunity to compensate for capacity shortfalls by targeting supervisory resources as effectively as possible to the areas,

activities and facilities where there is the greatest risk to patient safety and the quality of care. The approach allows for a better organisation of supervision, while at the same time building a common understanding of the quality of services and helping to promote good practices. The approach allows the supervisory authority to focus its attention and activities on poor quality services that need action to improve.

Supervisory organisations develop and continuously optimise their indicator systems using data from a variety of sources - data collected in the course of inspections, information provided by providers themselves, data from ongoing patient experience and satisfaction surveys, etc. Different countries give different priority to the type and sources of data - for example, in Denmark and Finland the focus tends to be on patient experience and satisfaction as identified through the various patient feedback mechanisms, in England and Sweden more importance is given to data on clinical performance and audit data, in Portugal, France and Estonia the focus is on self-assessment by the facilities themselves. Regardless of the model chosen, data are selected and aggregated in a way that allows supervisory authorities to make a preliminary assessment of whether the services provided by facilities are safe, effective and responsive to patients' needs.

Next, on the basis of the risk assessment, supervisory authorities shall identify priority control areas on an annual basis on which to plan their activities.

In all countries researched, supervisory authorities ensure public disclosure of the indicators used to assess risk. This approach allows facilities to use them to implement internal self-assessment and quality control systems.

Studied supervisory organizations use the results of their inspections mainly to introduce improvements and a culture of quality improvement in which the supervisory authority, patients and healthcare establishments are partners.

The practice of the European supervisory organisations shows that inspections often identify organisational problems, shortages of staff, equipment or finances, which can lead to various negative trends, but in all cases the key to resolving the problems identified is good

communication between the supervisory body and the stakeholders and a constant drive to find better solutions for patients and ways to improve the healthcare system.

5. FINDINGS

5.1. CONCLUSIONS FROM THE LITERATURE REVIEW

- Many authors believe that in order to initiate quality improvement processes, leaders need to ensure a supportive and encouraging culture in the organization that provides the necessary resources, time, and training for staff.
- Control implies continuous monitoring of the activities in their entirety and taking subsequent decisions, and making necessary adjustments to the process.
- Auditing can be seen as a tool to help improve the quality, effectiveness and efficiency of care provided to patients by measuring/assessing existing standards and changing them when necessary.
- The results of the audit should be made public to all professionals as well as to the public.
- A form of patient involvement in the audit process is the conduct of patient satisfaction surveys.

5.2. CONCLUSIONS FROM THE COMPARATIVE ANALYSIS

The results of this dissertation give us grounds to draw the following **main conclusions:**

- Countries are actively working to build integrated care systems that are primarily patient-centred and less about the functioning of the health system.
- The supervisory authorities seek to compensate for the shortage of resources, both human and financial, by developing supervisory mechanisms that are based on risk assessment, which facilitates the planning and targeting of supervisory activities to activities and facilities where there is the highest risk to safety and the quality of the services provided.
- For the purposes of risk-based control, supervisory authorities create indicator systems using a variety of data sources, both internal and external. Indicators are dynamic and continuously optimised.
- In countries such as England the focus is on data on clinical outcomes, whereas in others e.g. Denmark the focus is on patient satisfaction.

- Countries are seeking to replace ex-post control with proactive control and are developing models that call for ex-ante assessment of the safety, effectiveness and quality of services provided.
- The lack of an internal regulation detailing the methodology of inspections by inspectors is reported as a very serious shortcoming in the activities of the EAMS, which controls the quality of healthcare services.
- A positive trend is the active and targeted work to build trust and partnership between supervisory authorities, health care facilities and patients in order to introduce a culture of quality improvement.
- Most supervisory organizations are modifying mechanisms and methods of control so that the focus is on improving the system and less oriented toward penalizing the individual practitioner.
- Most countries rely on so-called "experts by experience" or trained patients in their control activities.
- It is good practice to set up systems where patient complaints are initially subject to review by the healthcare establishments.
- The results of the supervisory authorities' activities shall be made public, as well as the indicators used to assess risk. The aim is to ensure that establishments are informed and, where appropriate, have the opportunity to adapt or develop and implement internal systems for self-assessment and safety and quality control.

6. RECOMMENDATIONS

As a result of the study, the following recommendations can be made to:

1. EAMS

- In view of the conclusion made, develop tools such as a methodology for carrying out planned inspections as a result of a risk assessment.
- Planned control to be aimed at achieving specific targets which are set annually through risk assessment.
- Ensuring transparency and publicity regarding practices, actions and results of control activities, including good communication with the media and the public.
- Actively work with related international institutions to share best practices for effective supervision;
- Sharing information on good practices identified;

- Active work on the introduction of so-called "interactive supervision", which shifts the focus of control from sanctioning and punishment to promoting dialogue and cooperation through meetings, discussions, information sharing and feedback.
- Mandatory evaluation of the results of the control carried out, the extent to which the objectives have been achieved, and the need to take corrective measures.

2. Ministry of Health

- Take action on a legislative initiative to establish a national medical error reporting registry and introduce a healthcare establishments rating system.
- Initiation of legislative changes in the Healthcare Establishments Act to introduce an obligation for complaints from patients regarding the quality of medical care to be first examined by specialised units established at healthcare establishments and only in case of dissatisfaction with the response to be referred to the supervisory authority;
- Initiation of legislative changes in the Health Act and/or in the medical standards of the different specialties, related to giving a legal definition of the term "quality" and the elements of "quality";
- Together with the professional organisations and EAMS, develop and introduce a system of indicators for the assessment of the quality and safety of medical care;
- The newly created Directorate "Protection of Patients' Rights" at the Ministry of Health duplicates the functions of EAMS as a body that monitors the observance of patients' rights, in view of which we propose that it be reorganized by increasing the Agency's composition with its numerical composition.
- Initiation of legislative changes in the Healthcare Establishments Act and the Law on Transplantation in order to organizationally and functionally separate the activities related to organ and cell transplantation and assisted reproduction from the scope of competence of EAMS and to split them into a separate/self-standing structure.

3. Bulgarian medical association:

- In collaboration with scientific societies, develop rules for good medical practice and reliable and reproducible indicators for quality measurement and control, as well as a system for their follow-up;
- Incorporate patient safety training into all levels of education as a requirement for initial and continuing certification;

- Active cooperation between BLS and the competent supervisory organisations in the handling of cases related to professional ethics.

4. Health managers:

- Organization of trainings for more and more medical professionals on the concept of quality in healthcare, its assessment and management.
- Introduction of the risk-based approach in the activities of the healthcare facilities, periodic monitoring of risk factors and risk assessment.

7. CONCLUSION

As a result of the extensive analysis of the literature in the field of quality, safety, management, medical audit, as well as the control functions of the supervisory organizations studied, the thesis of this study is confirmed. It is undisputedly proved that the role and place of supervisory structures is crucial to assess and improve the quality of medical services, to achieve the mission of any health system, to achieve indivisible unity and interaction of health resources, management, quality of health care offered and health outcomes and satisfaction for the population.

As a good practice, the understanding that supervision in health care should contribute to solving problems, be focused on the evaluation of the results achieved, instead of being a tool for formal administrative control.

8. CONTRIBUTIONS

1. An extensive review of the literature in the area of control, audit and supervision of healthcare services is undertaken.
2. For the first time, a comprehensive review of the state and development of supervision/monitoring activities in the field of healthcare in seven European countries and in Bulgaria is presented.
3. The tools developed to perform risk-based control address the resource constraints of supervisory organisations by focusing control on those activities and systems that need improvement.
4. For the purpose of the benchmarking, indicators for assessing the organisation and performance of the supervisory organisations have been selected and applied for the first time.

5. As a result of the comparative analysis carried out, it has been determinated that the scope of activities of EAMA/EAMS is in line with that of the European supervisory authorities.
6. The analysis suggests that the focus of control should be shifted to prospective control.
7. Emphasis is placed on the need to take proactive and timely action to change legislation in order to provide a favourable legal framework conducive to effective control.
8. Patient feedback and dissemination of established good practices have been found to be very important steps in the process of improving the quality and perceived satisfaction of medical services.
9. The analysis identified the need for continuous training of both the organisations providing medical services and the supervisory staff.
10. The recommendations made point out ways to improve the efficiency of the EAMS's activities and reduce the imbalance between available resources and the volume of activity.
11. As a result of the extensive analysis of the literature, as well as the supervisory functions of the studied supervisory organizations, it is proven that the role and place of supervisory organisations is crucial for the evaluation and improvement of the quality of healthcare services, for the achievement of the mission of each health system, for the achievement of an indivisible unity and interaction of health resources, management, quality of health care offered and health outcomes and satisfaction for the population.
12. As a good practice, the understanding that supervision in health care should contribute to solving problems, be focused on the evaluation of the results achieved, instead of being a tool for formal administrative control.

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