MEDICAL UNIVERSITY OF SOFIA

FACULTY OF PUBLIC HEALTH

Department of "Health Policy and Management"

Rumen Stoynev Iliev

MEDICAL AUDIT AS A QUALITY MANAGEMENT APPROACH IN DENTAL PRACTICE

ABSTRACT
ON
DISSERTATION PAPER
FOR THE AWARD OF EDUCATIONAL AND SCIENTIFIC DEGREE "DOCTOR"

Field of higher education: 7. "Health and sports"
Professional direction: 7.4. "Public Health"
Doctoral program "Social Medicine and Organization of Healthcare and Pharmacy"

SCIENTIFIC SUPERVISOR

Prof. d-r. Zlatitsa Petrova

Sofia, 2023

The dissertation work has been approved and referred for defense by the departmental council of the "Health Policy and Management" department, Faculty of Public Health of the Medical University of Sofia.
The dissertation contains 142 pages and is illustrated with 23 figures, 29 tables and 2 appendices. The bibliographic reference includes 96 titles, of which 53 are in Cyrillic and 43 are in Latin. The numbers of the tables and figures do not correspond to those of the Dissertation work.

Scientific jury:

1. **Prof. d-r Ralitsa Zlatanova Zlatanova-Velikova, dm**
2. **Assoc. d-r Nataliya Mihailova Shtereva-Nikolova, dm**
3. **Prof. d-r Rosen Gospodinov Kolarov, dm**
4. **Prof. d-r Vladimir Hristov Gonchev, dm**
5. **Prof. d-r Kancho Trifonov Chamov, dm**

Reserve members:

1. **Prof. Krasimir Stoyanov Vizev, dm**
2. **Prof. d-r Hristo Stoyanov Bozov, dm**

The public defense will take place on 19.04.2023 in hall No. 7 of the Faculty of Public Health, UMBAL "Tsaritsa Ioana - ISUL" EAD, 8 Byalo More St., Sofia
Defense materials are available at the secretariat of the Dean's Office of the Faculty of Health Sciences, MU Sofia, UMBAL "Tsaritsa Yoanna - ISUL" EAD, 8 Byala More Street, Sofia city.

The defense materials are available at the secretariat of the Dean's Office of the Faculty of Health Sciences, Sofia University, Tsaritsa Joana University Hospital - ISUL EAD, Byalo More Street 8, Sofia and on the website of Sofia University: http://career.mu-sofia.bg/index.php

Introduction……………………………………………………………………4

PURPOSE AND TASKS, MATERIAL AND METHODOLOGY…………………………..4

RESULTS AND DISCUSSION………………………………………………..................7

Analysis of dental practices in European countries …………………………………7

Dental practice in Bulgaria…………………………………………………………...21

Executive Agency "Medical Supervision"EAMS - authority and control in dental practice ……………………………………..……………………………32

Algorithm of inspections of dental practices and results …………………………..33

Results of the inspections carried out by EAMA/EAMS for the period 2017-2019…………………………………………………………….................33

Questionnaire survey "Risk Management". Results and discussion ………………35

CONCLUSIONS AND RECOMMENDATIONS ………………………………..41

Conclusions from the literature review ……………………………………………41

Conclusions from an analysis of dental practices in European countries and dental practice in Bulgaria……………………………………………………………..43

Conclusions from the analysis of the results of the inspections carried out by EAMA/EAMS for the period 2017-2019...……………………………………………..44

Findings from the survey „Risk Management" …...45

CONCLUSION AND RECOMMENDATIONS…………………………………46

Recommendations…………………………………………………………...46

Conclusion…………………………………………………………………...47

Contribution …………………………………………………………………47

List of publications related to the dissertati………………………………………48

Introduction

Medical assistance, as a specialized human activity, has three main dimensions: type, quantity and quality, and their totality determines its ability to satisfy the health needs of the people who receive it. In recent years, with the "creation of a medical aid market", quality has also acquired a new meaning, becoming a major marketing tool. Quality assurance is a process that refers to concepts and methods for maintaining or improving the quality of services, in which systematic evaluation of performance against predetermined standards is used as a means of identifying problems in service delivery, introducing and tracking the improvement achieved. This is the reason why health care is increasingly being talked about as a field of increased danger with risks inherent in the provision of medical care such as morbidity, mortality, high costs, medical errors, the occurrence of adverse events and/or the provision of unnecessary health services . According to the National Health Strategy 2014-2020, the insufficient level of quality in the health care system is one of the reasons for the deterioration of health and people's dissatisfaction. Health care reforms do not lead to a serious improvement in the quality of various activities and do not meet the requirements included in the WHO definition:

1. Care to provide the best health result - maximum benefit and minimum risk for the patient

2. Excellent professionalism is demonstrated by all involved in the assistance

3. Efficiency and rational use of resources

4. High level of patient satisfaction and self-confidence

5. The best possible health outcomes

This necessitates the need to carry out specialized monitoring and supervision in dental medical care, so as to work in the direction of increasing and confirming the prestige of dental doctors, good medical practice and patient safety.

1. PURPOSE AND TASKS, MATERIAL AND METHODOLOGY

1.1. Purpose and tasks

Research thesis:

Through an analysis of the joint activity, cooperation and mutual assistance in the field of dental science and practice between the structures of BDA and the structures of the Executive Agency "Medical Audit"/EAMA to achieve the improvement of the quality and safety of medical care for patients, stimulating the contractors of dental care towards sustainable improvements in work, quality and increasing professionalism.

The purpose of the present study is to investigate the essence of medical audit in dental practice and specialized monitoring for sustainable quality improvement and increasing professionalism.

Tasks:

1. To track and analyze the main theoretical points related to the organization, activity, quality and control of dental care;

2. To analyze the information about dental practices in European countries;

3. To study Dental practice in Bulgaria-negotiation with the National Health Insurance Fund, payment, activity of BDA and CPE (Commission on Professional Ethics), quality of dental care;

4. To examine and analyze the activities of the Executive Agency "Medical Audit" / Executive Agency "Medical Supervision" as a specialized control body in the field of health care and that of the BDA as a class organization of dental specialists.

5. To explore the opinion of dental doctors about risk management in dental practice

6. To propose opportunities for improvement of the control based on the survey data.

1.2. Material and methodology

Depending on the scientific tasks set in this way, the object of observation, the units and their signs are specified.

The object of the present study are:

- ✓ Dental practice in the healthcare system
- ✓ Control activity of EAMA/EAMS and BDA /CPE in dental practice

The subject of the development is a study of the place, role and importance of the medical audit for improving the quality in the dental practice. The study is complex. The specific scientific tasks, object, units and signs of the observation are related to the specifics of the developmentEuropean countries and the Republic of Bulgaria.

The second component includes analysis of the audit performed by EAMA/EAMS and BDA/ CPE based on reports and monitoring of practices. Study period for EAMA/EAMS -2017-2019 for BDA - mandate of the Ethics Commission- 2015-2016, CPE of Metropolitan Regional College for mandate 2017-2020.

The third component is a survey of dental practitioners on risk management with the aim of improving the quality of dental care. There are 16 questions and they are structured in 4 groups:

- ✓ the danger for the dentist in cases where he performs medical intervention without informed consent

- ✓ need for joint cooperation between the Executive Agency "Medical Supervision" and the Bulgarian Dental Association
- ✓ prevention of complications, errors and accidents

ensuring the safety and security of both the patient and the dentist

The questionnaire was independently developed by the doctoral student. 128 dentists working in different practices were surveyed.Time of conducting the survey: 02. 2019 to 10.2019. in Sofia and the country.

Signs of the study are: gender, attitude to informed consent (necessity, content, sufficiency), conditions in dental practice, safety, communications, professional training, competencies.

The collected information was processed and analyzed statistically by sorting in statistical tables reflecting the sought patterns.

Signs of the study are: gender, attitude to informed consent (necessity, content, sufficiency), conditions in dental practice, safety, communications, professional training, competencies.

The collected information was processed and analyzed statistically by sorting in statistical tables reflecting the sought patterns.

Research methodology.

The methodological basis of the dissertation is a complex of general scientific and special scientific methods and approaches for conducting scientific research, which complement each other. The following methods were used:

- ✓ Documentary method - on the basis of the official reports of EAMA/EAMS, Ethics Commission of BDA, in order to create a deep understanding, the following were studied: scientific publications on the problem in national and international literary sources/regulations;
- ✓ Conceptual analysis - to clarify the terminological issues related to the topic of the dissertation work;
- ✓ Analysis and synthesis;
- ✓ Comparative method;
- ✓ Sociological method - survey;
- ✓ Statistical methods;

  Cronbach's α for all 36 items was 0.86

Internal consistency was examined using Cronbach's α. Values above 0.70 are considered satisfactory. Cronbach's α. for the conducted survey it is 0.86.

Reliability Statistics

Cronbach's Alpha	N of Items
,860	16

Internal consistency was examined using Cronbach's α. Values >0.70 were considered satisfactory

- ✓ Graphical analysis – for visualization of the obtained results.

The specified methods of conducting the research complement each other, which allows the information to be assessed in many ways.

2. RESULTS AND DISCUSSION

2.1 Analysis of dental practices in European countries

2.1.1 Types and characteristics of dental practices

Countries in Europe show very large variations in how general health care is provided (for example, in terms of ownership of health facilities, workforce structure and the balance between primary and secondary care), dental care provision in most countries is practitioner-dominated, working in private practice ('private' or 'liberal') or 'general practitioners' without being salaried. In most of the EU, they represent nearly 90% of practicing dentists. Several countries (Belgium, Iceland, Luxembourg, Malta and Portugal) report close to 100% of dental care provided by this method. Only in countries where there is a large, state-funded fund for dental treatment are the numbers of general practitioners in Dental Medicine lower.While public services are usually focused on providing care for special groups such as children, private practitioners are arguably the main, and often the only, provider of care for the elderly population.

Liberal (general) practice

Methods of opening a liberal or general practice are similar across Europe, with younger dentists often employed as associates or assistants before they can afford to organize their own practice. However, in countries where private practice dominates (eg France, Belgium and Norway) it is very difficult to start your career as an assistant or associate. Government incentive schemes aimed at persuading dentists to relocate to sparsely populated areas are also very rare. The importance of dental doctors as a liberal profession was highlighted by the adoption of the EU Charter for the Liberal Professions, proposed by the Council of the European LDD (Liberal Dental Doctors) and jointly developed and adopted with the representatives of the organizations of European doctors, pharmacists and veterinarians. Most dentists, like any other business, need to take out business loans to purchase a practice. By buying the existing practice, they usually also buy a list of patients. Many states have some regulations governing the location of premises where Doctor of Dental Medicine can practice, but there are usually only general planning requirements. In general, throughout Europe, general practice dentistry is seen as a small business, with only one, two or a

few dentists practicing together (in Greece only since 2001 can dentists share a clinic or dental chair). This is why there are large dental cluster group practices - for example in the UK one company owns over 500 practices employing several thousand Doctor of Dental Medicine.

Public dental services

For the purposes of describing the provision of health care outside of liberal (general) or private practice, we describe this as public dental services. However, this is not entirely accurate as the lines between employment/paid Doctor of Dental Medicine and privately owned/publicly owned facilities have been blurring in recent years. So, inside there are salaried dentists working in private practice - usually as assistants or associated with the owner of the practice. While most general dentists own or rent their premises from the private sector, in some countries (e.g. Estonia) they may hire the facility from the local health authority or municipality - which may even supply the practice with support staff, equipment and materials. Overall, around 11% of EU/EEA dentists work in the public sector. This figure has hardly changed since the last edition of the handbook. In some countries, the term "public dental services" also applies to practitioners working within that country's public health insurance system. For the purposes of description in this study, this term applies to those working in (usually) salaried practice subsidized by the Equal Insurance Scheme/Fund.

Community clinics

Most countries have some form of civil service that is publicly funded. Such type of health services/polyclinics are particularly strong in the Nordic and Baltic countries, where, with the exception of Estonia, a large proportion of active dentists work in such. There are no public clinics in 6 countries Belgium, Ireland, Liechtenstein, Estonia, Czech Republic, Luxembourg,). In many countries, dentists work in such clinics only part-time - either because they are women who stay at home to take care of their families or because the low wages in this type of establishment necessitate employment in private practice as well. Common services provided by most countries with these clinics include emergency care, public dental health, preventive services and postgraduate training. These services are available to all citizens and are often free of charge. General dental care may also be available to certain classes of patients – children under 18, medically compromised patients and low-income adults. These services are also often provided free of charge.

Hospital dental treatment

The strict definition of a hospital is not the same across Europe. But for the purposes of this section establishments are considered which have facilities for patients who are being treated for acute or chronic diseases, have facilities for the stay of patients for one or more nights, and are capable of receiving walk-in patients. Dental faculties with hospital wings are not included in this overview. All countries have hospitals where trauma is treated, oral-maxillofacial surgery and pathological autopsies and examinations are carried out. Most also provide postgraduate training for potential

surgeons. Hospitals are private and public that provide dental care. Dental care providers are usually paid in public hospitals, but in most countries they are also able to work extra hours in private practices.

Dental activity in the faculties of dental medicine.

Some dental care is provided in dental schools by DDM habilitation assistants and (in most countries) by dental students. However, the quantitative share of this type of treatment is believed to be very limited.

Dental work in the armed forces

Many EU/EEA countries have national service in the armed forces. These countries, and many of those with volunteer armed forces, have formal responsibilities for providing oral health care for their personnel. They are provided by their Dental Departments or by local arrangements with community clinics. In Germany, Poland and Great Britain, however, the armed forces have well-developed structures and are served by a large number of dentists.

Illegal Practice of Dentistry

There are no reports of the illegal practice of general dental practice throughout the EU/EEA. However, there are reports of dentures being made and teeth whitening done by individuals who are not legally able to provide such services. Several countries - Belgium, France, Greece, Hungary, Ireland, Italy and the UK - report illegal denturism, although with the regulation of (legal) clinical dental technicians in the UK in 2008. And VVT (Belgium) reports that there is a trend towards the legalization of dental tourism in Belgium. Clinical dental technicians / dentists can practice legally in Denmark, Finland, the Netherlands, parts of Switzerland and the UK - thus reducing the potential for illegal practice.

Professional ethics

Dentists in every European country must comply with the relevant ethical principles. Whether formally expressed as laws, oaths or written guidelines, these principles apply to their relationship with patients, other dentists and the general public. The most common method of providing ethical guidance to dentists is through the drafting of a Code of Ethics. This is usually drawn up and enforced by the National Dental Association or in some countries by a separate regulatory body (for example, as in France, Iceland and the United Kingdom). The enforcement of these PE codes is usually the responsibility of ethics committees at the local level. The professional and other conduct of dentists is usually also governed by specific laws (such as the dental acts in Norway and Iceland), more general medical laws (for example in many of the new EU member states and in Austria, where dentists must also accept " the Hippocratic Oath'), as well as laws regarding professional and business conduct.

Standards and monitoring

Although the threat of patient complaints is probably still the strongest 'check' on standards of good quality care, more and more health systems have other mechanisms for monitoring Doctor of Dental Medicine practitioners. These include external “prior approval” of expensive or complex treatments, incentives or rules for participation in ongoing after graduate studies, and more basic control over the level of billing and treatment patterns of individual practitioners. Some of the widest variation in dental practice across Europe relates to monitoring standards. In most countries, the monitoring is not of the quality of care, but simply an administrative control to ensure that the patient has been billed the correct amount for the type and volume of treatment received.

Advertising

There is huge variation across the EU/EEA as to what constitutes "advertising", in its true sense, when applied to the publication of information about doctor of dentistrys and their practices. So in many countries even going into the Yellow Pages, classified telephone directories, etc., can count as advertising. In the following countries the rules are very strict and practitioners are prohibited from any public form of communication: Belgium, France, Greece, Iceland, Malta, Portugal, Romania, Slovakia. Advertising when first opening a dental practice is only allowed in Croatia, Cyprus and Slovenia. Only limited advertising is allowed in Hungary.

Websites

Unlike advertising rules, almost all countries allow the use of dental practice websites - Luxembourg and Malta are not. The guidance on the e-commerce directive was developed by CED.

Data protection

All EU countries, Norway and Switzerland have adopted the EU Data Protection Directive in their national legislation. National legislation in Iceland covers this area for Doctor of Dental Medicine practitioners.

Indemnity insurance

In all EU/EEA countries, professional indemnity insurance ensures that there is adequate compensation for patients who have been harmed in any way. This protects practitioners from bankruptcy after paying compensation and legal costs if a claim arises against them. However, in some countries this compensation/insurance is not mandatory.

Corporate practice

Most states allow dentists to establish their practices as limited liability companies (bodies corporate). Only in Germany, Ireland and Malta are they completely restricted. No information on Luxembourg.

Health and safety at work

All EU/EEA countries have rules to protect healthcare workers and patients, such as the prevention of cross-infection. An increase in the number of items and the use of single-use materials only - eg needles and gloves is widespread. Vaccinations against certain diseases, especially hepatitis B, are recommended for dental workers, and in many countries vaccination against hepatitis B is mandatory.

Ionizing radiation

All countries have regulations related to the use of X-ray equipment, which usually include mandatory regular inspection of the machines and frequent registration in a central database. All Doctor of Dental Medicine study the properties of ionizing radiation. However, in most countries the taking of radiographs is not legally restricted to dental practitioners. X-ray practices as well as other dental professionals can perform this manipulation if they have the necessary education and training.

Dangerous waste

Again, all countries have regulations relating to the storage, collection and disposal of waste, including clinical waste. Of particular importance to dental practices is the collection of amalgam waste. Every state now recommends the installation of "Amalgam Separators" which collect the amalgam waste before it reaches the main drainage system. However, most countries insist that they be made a mandatory requirement. Sometimes this is only necessary in newly installed structures, but often it is a mandatory requirement in any practice, new or not. Only Denmark has been added to this list since 2008.

2.1.2 Dental practices in European countries - registration and quality of care

Croatia

Quality of care

State authorities provide rules for the premises, equipment and qualifications necessary to provide dental care. The State Insurance Company (HZZO) provides a list of services, the volume and price of each service provided by the state. The Croatian Dental Chamber describes the standards necessary for the performance of these services. Billing is actively checked by HZZO to ensure that invoices reflect the amount of work performed. X-ray laboratories and their equipment are strictly monitored by the authorities. Patient rights are protected by the Patient Rights Protection Act (2004). The Croatian Chamber has an expert committee with a quality control system whether it concerns the private sector or through the HZZO.

Registration

To register in Croatia, a dentist must have a recognized degree or diploma awarded by a university and have completed a year of compulsory training or "residency" under the supervision of

experienced dentists. At least 6 months of this training is undertaken in a dental school and 6 months in one of the experienced private or training offices. After passing the exam, the Doctor of Dental Medicine receives a license from the Croatian Chamber and can work independently.

Cyprus

Registration is under the Dentists Registration Act 2004. In order to practice dentistry in Cyprus, registration with the Cyprus Dental Council is first mandatory for recognition of one's title. Then, in order to practice, he/she must be registered with the Cyprus Dental Association (the professional body), so all dentists are members. If an EU dentist wants to be established in Cyprus, he must also be registered with both CDC and CDA, but for a dentist who wants to provide services for a limited period of time, only CDC registration is required.Readiness to practice / Disciplinary issues

Patient complaints are presented to the Cypriot Dentist, the Association and the Court, depending on the nature of the complaint. The Disciplinary Committee of the Cypriot Association assesses the complaints. Dentists from both the public and private sectors are members of the committee.

Czech Republic

Quality of care

The dental chamber intervenes when a patient complains about the quality of care. The complaint can be submitted to: the Health Insurance Company, the Dental Chamber to the Regional Authority. Final appeals are processed by Regional Dental Boards. The authority to check a dentist's professional malpractices or ethical wrong decisions is carried by the relevant professional disciplinary bodies - the Honorary Councils of the Regional Dental Chambers and the Honorary Council of the Czech Dental Chamber.

Readiness to practice / Disciplinary issues

If a valid complaint is filed with the regional Honorary Council of the Czech Dental Chamber, the results of the complaint may be a reprimand, a fine or even loss of license (the dentist cannot be suspended from practicing immediately). In any case, a serious violation of the law can be taken to court and even lead to imprisonment. The appeal is heard by a professional body - the Regional Audit Board of the Czech Dental Chamber. An appeal to the highest disciplinary body of the Czech Dental Chamber is possible.

Denmark

Quality of care

Regional councils monitor the standards and costs of oral health services. This is mainly done through a treatment audit. Each dentist must submit a number of treated cases to claim a public subsidy. Any dentist who performs specific treatments more or less than 40% of the average for

the region must provide an explanation. In principle, the quality program includes all clinical pathways for patients in healthcare facilities.

Readiness to practice / Disciplinary issues

There are two systems to which patient complaints are addressed. One relates to complaints against dentists working with the 'consent of dental care for adults (Tandlægeoverenskosten) and others to all other complaints (Patientombuddet). The system for submitting complaints to Tandlægeoverenskost is managed in the regions by committees. Sanctions can range from a reprimand to a recommendation that the license to practice be revoked. The system under Tandlægeoverenskosten also deals with monetary issues, but it concerns compulsory patient insurance and grants compensation to proven affected patients. The Patientombuddet service deals with complaints from one dentist to another.

Estonia

Readiness to practice / Disciplinary issues

If the treatment is unsatisfactory to the patients, they can file a claim with the Consumer Protection Bureau. For disciplinary purposes, complaints from patients are investigated through an ad hoc Committee on Quality of Treatment, which is appointed by the Ministry of Social Affairs and Health Care Supervision. The patient can also write a complaint to the Consumer Protection Commission, but they forward the complaint to the Health Care Surveillance Department. There is one dentist in the Treatment Quality Commission who is appointed by the Ministry of Health as a dental advisor. The dental advisor is a board member of the Estonian Dental Association. To appeal against what they consider to be an unfavorable decision, the patient or the doctor/dentist can appeal to the Court.

Phillandia

Quality of care

Although government authorities give recommendations to dentists, for example on obturation materials or hygiene protocols, standards of dental care are not actively followed in Finland when it comes to private practice. The only routine system is a random check of invoices by KELA - the local NHIF. The average price per patient is evaluated and it is monitored whether the invoiced amount corresponds to the volume of manipulations performed. The care provided in health centers is subject to quality control. Patient complaints are usually dealt with by the National Wellbeing and Health Authority or a Complaints Board supplemented by a Patient Ombudsman. Also, since the Patient Injury Act came into force in 1987, a patient insurance fund was created that can compensate for injuries sustained during treatment.

Readiness to practice / Disciplinary issues

The supervision of the practice of medicine and dentistry is carried out by the National Supervisory Authority for Welfare and Health, with about 15 complaints from Doctors of Dental Medicine being submitted to it each year. Another avenue for filing a complaint may be the local executive. The consequences of an upheld complaint can be: 1. a written warning, a reminder of the obligation to exercise adequate care, 2. a warning or even a restriction of the right to practice dentistry. There are also local ombudsmen for consumers. In 1993, the Patients' Rights Act came into force.

France

Quality of care

The Statute of Socially Insured Citizens allows patients to request an expert opinion on the treatment provided, in case he/she is not satisfied with the treatment or if necessary an examination is carried out. Complaints can be sent either to the Social Security Services or to the Ministerial Council of the Ordre National or following the standard legal procedure. In case of litigation, the practitioner may be assisted by a colleague. However, no law provides for a "guarantee of result".

Readiness to practice / Disciplinary issues

When it comes to a conventional conflict, the case is considered by a committee composed of Doctors of Dental Medicine and representatives of the professional organizations that have concluded a contract. Sanctions can range from financial penalties to temporary restriction of practice or removal from the register.

Germany

Quality of care

Standards for dental care are overseen by a federal commission for dental care (Gemeinsame Bundesausschuss). Both the hospital funds and the federal dental care authorities (Kassenzahnärztliche Bundesvereinigung) are represented on this committee. Its main role is to determine the range of necessary treatments to be covered by the compulsory sickness fund. Routine monitoring is carried out by KZV and consists of checking invoices and volume of work performed by each dentist. The same monitoring framework applies to patients who pay the full cost of treatment themselves and are subsequently reimbursed by insurance companies. The threat of patient complaints has a direct effect on the quality of care for most dentists.

Readiness to practice / Disciplinary issues

If a patient complains about treatment, the chamber and the KZV have complaint committees. When a complaint is lodged, a second opinion is sought from an experienced, impartial Doctors of Dental Medicine appointed by the local dental chamber. If this dentist determines that the initial care was unsatisfactory, then the manipulation must be repeated at no additional cost to the patient. In both complaints procedures, the dentist has the right to appeal to the Complaints Committee.

Sanctions from the professional law court can be: verbal or written warning, administrative fine (up to 50,000 euros) or temporary or permanent revocation of license.

Greece

Quality of care

The national government has the primary responsibility for payment of fees, quantity and quality of work and together with the Hellenic Dental Association - HDA - monitors the ethical behavior of dental practitioners. For manipulations paid for under social security schemes, standards of dental care are monitored by part-time NHS employed dentists.

Readiness to practice / Disciplinary issues

Serious complaints from patients are referred to the Central Disciplinary Board of the Ministry of Health and Welfare and the NHIF, there are also disciplinary boards in hospitals and in local health centres. In addition, the disciplinary panels of each local dental association hear complaints. When complaints are not due to misunderstandings, a patient can be examined by an expert dentist, a university representative. The theoretical final sanction for either a private practitioner or a dentist working with the NHIF is the withdrawal of the right to practice. Dentists have a right of appeal within this process to the Disciplinary Commission of the Hellenic Dental Association.

Hungary

Quality of care

There is a mandatory internal quality assurance system for those dental care providers contracted by the National Health Insurance Company.

Readiness to practice / Disciplinary issues

Patient complaints about public or private care can be taken to dental providers, the National Public Health & Medical Officers' Office or the courts. (Ethical complaints are reviewed by the Ethics Committee of the Medical Chamber). There are authorized regional legal representatives for patients. The most serious penalty is that a dentist may lose their license to practice, but this is very rare, or they may also be reprimanded. An appeal to a higher instance and finally to the courts is possible. Only the Hungarian Ethics Court can revoke a practitioner's license to practice.

Iceland

Quality of care

The quality of care is monitored by the chief physician on duty in the Directorate of Health, mostly following patient complaints. Icelandic Health Insurance also performs basic statistical analyzes of data on treatment patterns provided by each dentist and each practitioner. For most minor

problems, Icelandic health insurance alerts the dentist; more serious cases are referred to a Liaison Committee, where both the Icelandic Health Insurance and the Dental Association have representatives.

Ireland

Quality of care

For treatment provided under a government scheme, the standard of dental care is mainly monitored by the funding body, the Central Paying Boards of the Department of Social Affairs. This is done in two ways. First, dentists' treatment protocols are monitored to see if they differ significantly from existing norms. Second, the Department of Social Protection uses dental reviews to check the quality and quantity of dentists' work. Complaints related to private dental care are usually addressed to the treating dentist directly from the first instance. A Voluntary Mediation Service was established by the Irish Dental Association in 2012 and has proven to be very successful in resolving disputes.

Italy

Quality of care

"Clinical guidelines" have been developed by several universities and scientific and professional associations, including ANDI and AIO. In 2012, they were approved for use by the Ministry of Health. Both public and private practices are inspected or 'licensed' by the District Health Service (ASL), which means they must meet certain professional and structural standards, which may vary from region to region. In addition to the mandatory standards, some regions have developed and enforced additional accreditation standards to allow work under contract to NHIF.

Standards

There is no formal monitoring in any sector except in case of patient complaint. Complaints from patients from private practice are directed to the relevant ethics committee. In the Public Service, they are first examined by a clinical dentist, who theoretically has the power to revoke the dentist's license.

Latvia

Quality of care

The competent authority that maintains the registration of dentists and their accreditation for dental practice (every five years) is the Health Inspectorate (HI), in cooperation with the Center for Dental Medicine. Since 2001, this agency has been working in accordance with national regulations - with instructions regarding the working space, appliances and dental technology, imposing standards for minimum requirements for dental practice. An evidence-based, methods and technology document was developed in 2002 and has been in force since 1 July 2003, in all registered

practices. This document is intended to motivate all dental staff to attend Post Graduate Training courses. The quality of work is evaluated by HI inspectors and experts of dental associations.

Readiness to practice / Disciplinary issues

In case of complaints, examinations are carried out by the Health Inspectorate (HI) with the participation of experts from professional associations. Reviews are mainly conducted in cases of complaints, which most of the time are related to obtaining financial compensation. There is a certain procedure to protect the rights of patients. The professional organization may assign the dentist additional postgraduate training or, in special cases, may decide to revoke the professional's license. Dentists have a right of appeal.

Lithuania

Readiness to practice / Disciplinary issues

A patient complaint is possible, which can be submitted to the Health Insurance Company, Dental Chamber, Ministry of Health of the Republic of Lithuania, State Medical Audit Inspection (SIMA). In case of violation of professional ethics or rules for practicing dentistry or causing harm to a patient, there are a number of penalties, which are usually applied by the ethics committees of the dental chamber - in regional branches of the chamber.

Luxembourg

Quality of care

Standards of dental care are monitored by an independent body called Contrôle Médical, which employs three dentists who check the standard of care. Dentists whose model and cost of care differ significantly from the average may be investigated. An independent body - the Supervisory Commission investigates any complaints.

Malta

Quality of care

An annual inspection by health inspectors ensures that all dentists and clinics are registered and operating in accordance with local regulations set by the local standards authority.

Readiness to practice / Disciplinary issues

Maltese dentists are regulated by the Health Professionals Act, which came into force on 21 November 2003. A complaint can be lodged by anyone, including persons not involved in the case. A simple letter is enough to start an investigation. In the public sector, the complaint is submitted to the Customer Service Department of the Health Department. In the private sector, the Medical Council of Malta deals with such matters.

The Netherlands

Quality of care

The quality of dental care is monitored by the profession in a variety of ways and emphasis is placed on quality assurance and improvement rather than control. Quality improvement is achieved through continuous training, peer review and development of standards and certification. The Health Professions Act (BIG Act) was introduced for all health and dentistry on 1 December 1997. The Act had four significant implications for the Doctor of Dental Medicine, a change in the revised qualification regulation, a new registration under the Act, quality assurance and a revised disciplinary code. The act replaced a number of existing and outdated laws.

Quality register

In 2007, the Stichting Kwaliteitsregister Tandartsen (Institute for the Dental Quality Register) was established with the aim of creating transparency in the quality of dental care and thereby contributing to patient safety. To achieve this, the Stichting maintains a register of dentists. Since July 1, 2007, this quality register has been available to the public.

Readiness to practice / Disciplinary issues

Patient complaints can be handled in three ways. There is a general disciplinary law for health professions. Under this law, complaints are heard by one of five regional medical disciplinary panels. The board consists of 2 lawyers (including the chairman) and 3 dentists. Sanctions can be a warning, reprimand, fine or suspension / removal from the register.

Norway

Quality of care

Standards in dental practice are guided by several different types of oversight. The Supervisory Board of the Norwegian Board of Health is responsible for monitoring in the field of DM. Monitoring is carried out by designated county executive officers in each of the 19 counties. They use designated dentists to supervise and evaluate dental practitioners against mandated standards, quality assurance programs, etc. The Norwegian Consumer Council is responsible for publicizing Doctor of Dental Medicine price lists and offers to patients. The Good Clinical Practice guidelines were introduced by the Norwegian Directorate of Health in 2011.

Readiness to practice / Disciplinary issues

Cases involving violations of the code of ethics are initially handled by the board of the local branch of the Dental Association. If the dispute is not settled there, the case is brought to the Council on Dental Ethics. The Council may - in cases of violation of the Code of Ethics - take action, of which the worst case scenario is to propose to the NDA Council to terminate the

membership of Doctor of Dental Medicine in the Association. Patient requests are not processed. Liability is considered a separate matter and does not form part of the Board's jurisdiction.

Poland

Quality of care

There are regular inspections as well as those following a complaint. In most cases, they are initiated by a complaint filed by a patient.

Readiness to practice / Disciplinary issues

The disciplinary procedure is determined by the Health Professions Act. Disciplinary sanctions are imposed by a decision of the Medical Court, which is part of the chamber. The regional and supreme medical commission consists of dentists and doctors. However, cases strictly related to dental practice are heard only by dentists. Other ethical code issues may also be taken up for review by physicians. Audits for professional responsibility and for the regional courts in each of the 24 regional courts are done with at least one examiner on the bench of the Supreme Court, who supervises compliance with the rules of the code of ethics. The Polish Chamber also employs people who are not medical specialists, but provide advice and assistance to dentists and doctors.

Portugal

Quality of care

The quality of care provided is monitored by the OMD and in most cases, if fraud or illegal practice is detected, those responsible are prosecuted by the joint action of several public health authorities. Patient complaints are handled in two different ways: by the professional organization and by the courts. The OMD regularly issues clinical and professional regulatory guidance and a good practice handbook.

Readiness to practice / Disciplinary issues

If prima facia evidence is found to support any complaint, it may be referred to the OMD Ethics Board for investigation. The Council has the power to reprimand the dentist, suspend him from practice for a period of up to five years or terminate his membership of the OMD, be referred to the OMD Ethics Board for investigation. The Council has the power to reprimand the dentist, suspend him from practice for a period of up to five years or terminate his membership of the OMD.

Romania

Quality of care

Only after a patient's complaint, the Joint Commission (CSHIH and the Romanian Dental Colleges) can give an assessment of the quality of work in the NSHIH system. Outside the NSHIH, in the liberal system the quality of dental work can only be judged by the RCDP (Romanian College of Dental Practitioners). From the point of view of quality, the County Health Insurance Fund has the right to regularly monitor the activities of contracted dentists through an inspection committee composed of CSHIH employees, which may or may not include a dentist member.

Readiness to practice / Disciplinary issues

A complaint from a patient is first examined by the Local Council of the Romanian College of Doctor of Dental Medicine (RCDP) and then referred to a professional expert committee of the RCDP. Complaints that are not satisfied can be referred to a panel of dental experts nominated by RCDP members with more than 10 years of experience. A committee of dental experts of the RCDP analyzes the case and determines whether the complaint is justified. The RCDP imposes tiered penalties that can ultimately result in a dentist being suspended from practice. A complaint can be taken to the justice system.

Slovakia

Quality of care

Patients expect high-quality and long-lasting functional treatment, but this depends on the personal responsibility, skills and professional knowledge of the dentist. Dentists who work under an agreement with an insurance company may be supervised by examining dentists. These are dentists employed by an insurance company; they control, for example, the invoices that dentists send to an insurance company from a professional (clinical) point of view. The patient can submit a complaint to an "auditing" dentist, to the municipal services, to the Control Committee of each regional chamber of dentists, to the state department of supervision and control of the Ministry of Health or directly to the court. As of 2008, a control body (the Supervisory Body of Health Care) was established, which is responsible for the control of professional violations of the provided health care.

Readiness to practice / Disciplinary issues

Sanctions against dentists who violate the code of ethics are set out in the law. This may lead to a censure. If the offender repeatedly fails to comply with the regulations, he is fined from 300 euros to 1,470 euros for violating the duties of a member of the Slovak Chamber of Dentists. Sanctions may be imposed multiple times. The ultimate sanction is to be expelled from the Slovak Chamber of Dentists. This fact is announced by responsible authorities (health care monitoring body).

Slovenia

Quality of care

For dentists who have agreements with HIIS, the amount of work is monitored by HIIS. They have an annual contract with a maximum they can fulfill. For private dentists, the work is monitored by the government in the form of the market inspection. For all dentists, the quality of work is monitored by the dental chamber. There are routine checks and also if someone makes a complaint (patient, other colleagues, insurance companies or the Ministry of Health), the Expert Medical Committee of the Chamber carries out the investigations. The Chamber has an Expert Medical Commission that investigates complaints against and the quality of care provided by Slovenian dentists. The professional dental committee consists of three Doctor of Dental Medicine from different specialties. They cannot award compensation to injured patients.

Spain

Quality of care

There is no official monitoring of the quantity or quality of dental care.

Readiness to practice / Disciplinary issues

If a patient wishes to complain about a dentist or an entire practice, it can be either to the Regional Board or the Municipal Consumer Protection Services in the town halls or directly to the courts. Complaints are considered by a Deontological Commission, which consists only of dentists. These commissions can arbitrate, issue private or public warnings, warn the dentist or, in severe cases, go to court to remove him from the register.

Sweden

There is a dental care law that states that all Swedish citizens have the right to quality dental care and good dental health under equal conditions. The standards are monitored by the regional Departments of the National Board of Health and Welfare (NBHW or Socialstyrelsen). The authority has issued a regulation determining the quality of services. The dental service also operates using a system called 'Lex Maria' where all incidents that have caused or could cause serious injury must be reported. The Medical Liability Board (HSAN) is the only body that can apply sanctions. There are four alternative sanctions: a warning, freezing of the license for a trial period or the license being terminated. The most common reason for a dentist to lose their license is illness - less common is crime and lack of skills. An appeal against a decision made by HSAN can be made to the Stockholm District Court.

2. 2. Dental practice in Bulgaria

Dental health is an essential part of the general state of health of every person, which explains and necessitates the creation and existence of a specific system of rules regarding the quality of dental care. Under the conditions of dynamic changes in health care, the basis of the health reform is the independent dental practice, which contains all the basic health and support activities characteristic of outpatient dental care. These activities need effective management, regardless of whether the

dentist works in a solo or group practice, in a dental or medical-dental center. In all forms of free practice, the dentist bears moral, administrative, civil and criminal responsibility, as well as responsibility to the professional organization - Bulgarian Dental Association (BDA). The health activities of dental medicine are aimed at the treatment of dental diseases, which by their nature, complexity and complexity include medical and diagnostic measures to satisfy the dental care sought by the population, which prevents the occurrence of new dental and general diseases, as well as interaction with other subsystems in health care and beyond, in providing complex dental health.

2.2.1 Negotiating with healthcare providers

Dental health is an essential part of the general state of health of every person, which explains and necessitates the creation and existence of a specific system of rules regarding the quality of dental care. Under the conditions of dynamic changes in health care, the basis of the health reform is the independent dental practice, which contains all the basic health and support activities characteristic of outpatient dental care. These activities need effective management, regardless of whether the dentist works in a solo or group practice, in a dental or medical-dental center. In all forms of free practice, the dentist bears moral, administrative, civil and criminal responsibility, as well as responsibility to the professional organization - Bulgarian Dental Association (BDA). The health activities of dental medicine are aimed at the treatment of dental diseases, which by their nature, complexity and complexity include medical and diagnostic measures to satisfy the dental care sought by the population, which prevents the occurrence of new dental and general diseases, as well as interaction with other subsystems in health care and beyond, in providing complex dental health.

Phase I – National Framework Agreement

The National Framework Contract (NFC) provides the normative framework for concluding individual contracts. It is developed separately for doctors and dentists. It is implemented annually, and from 2020 it is valid for three years, preparing the financial conditions and requirements for the work of the contractors in the following years. Two parties participate in the two national contracts - the NHIF and the professional organizations of doctors and dentists.

Phase II – Contracts between the NHIF and the individual contractors

Contracts are concluded between the director of the RHIF (as a representative of the NHIF) and the individual contractors of health care - public and private health/treatment facilities and private practitioners, dentists in the relevant region - district. The conclusion of contracts for the provision of outpatient care with doctors and dentists working in a hospital is provided as an exception, provided that there are not enough private practitioners of the same specialty in the area and the hospital's operations are not disrupted. Scientific activity and training of medical specialists are not subject to negotiation. Representatives of NHIF for signing the NFC are members of the Supervisory Board and the Governor of NHIF. The national framework contracts are adopted by

a majority of not less than 7 representatives of the NHIF and 7 representatives of the professional organizations of the doctors, respectively of the doctors of dental medicine. The national framework contracts are adopted no earlier than the promulgation of the NHIF budget for the following year and no later than the last working day of the current year. The Minister of Health approves the adopted NFC within 14 days of their presentation and promulgates them in the State Gazette. When the National Framework Agreement for medical and, respectively, dental activities are not accepted under the conditions and within the terms set in this law, the current NFC shall apply.

Scope of the National Framework Agreement (NFA)

The scope of the National Framework Agreement is generally regulated by the Health Insurance. Detailed content of the basic packages for primary, specialized, hospital and dispensary care is published by the Ministry of Health in special regulations and this must precede the negotiation and signing of the contract. The National Health Insurance Fund pays for the provision of the types of medical and dental care under Art. 45, para. 1 HHI, with the exception of dental assistance and transport services for medical reasons.

2.2.2 Requirements of the NHIF for concluding a contract for dental activities

In general, in the sense of the new National Framework Agreement 2020-22 for dental activities, the conditions and procedure for concluding contracts with the National Health Insurance Fund (NHIF) as a source and guarantor of payment for performed medical dental activities for health insured persons consist of in general and special ones. According to Art. 16 of the National Framework Agreement, as general terms and conditions, the following conditions should be specified for dental care providers: a) they are not deprived of their rights to exercise a medical profession in the Republic of Bulgaria - for dental doctors who lead, respectively work in the medical facility; b) the doctors of dental medicine who lead, respectively work in the medical facilities, are members of the relevant Regional College of the BDA; c) dentists - citizens of member states of the European Union, and other members of the EEA, Switzerland, as well as of third countries, meet the conditions of the law and the National Framework Agreement; d) the dentists who work in the relevant medical facility for outpatient care are not members of the Territorial Expert Medical Commission (TEMC)/National Expert Medical Commission (NEMC). The conditions that go beyond the scope of the above are those that are characterized by an exclusively administrative and formal nature, are defined as special and are explicitly listed in the National Framework Agreement 2020-22. A party to a contract for the provision of outpatient dental care with the NHIF can be a medical facility that meets the general conditions under Art. 16, paragraph 1, item 1 and on special conditions.

2.2.3. Paying dentists

Until 2003, dental doctors (dentists) were paid for activities performed (with a standard time for each) within a limited number of working hours per month (1-2 hours per day) without additional payment from the patient. Also, people choose their dentist. Problems piled up with huge waiting lines, equalization of payments for both good and bad dentists. In 2003, the Congress of Dentists adopted a new liberal concept for the provision of dental care, in which the National Framework Agreement 2003 agreed on a system of providing dental care (at every dentist in the district), but under conditions of co-payment by the patient for most services . Children's and preventive services were negotiated at a lower co-payment or no co-payment. The method of payment by the NHIF was agreed to be for each service rendered. If the planned budget is exceeded or not used, the payment by the NHIF for the dental services is reduced/increased after negotiations. According to the National Framework Agreement for dental activities 2020-2022, the NHIF pays for one comprehensive examination of health insured persons over 18 years of age and up to three treatment activities, and for persons under 18 years of age – a comprehensive examination and up to four treatment activities.

2.2.4 Structure and activity of Bulgarian Dental Association BDA

The Law on Class Organizations and the Statute of the BDA establish and constitute the bodies of the Union:

Governing bodies: The Congress consists of representatives of their regional colleges, who are elected by their general meetings of the regional colleges at a rate of representation of one delegate per 25 members of the BDA.

Board of Directors:

According to the law, it is headed by a chairman, chief secretary and deputy. Chairmen. Manages the organization's property, keeps the register and directs the activity in the performance of its functions. The Statute of the BDA regulates territorial representation in the Management Board by including representatives from all 28 regional colleges of the BDA. The statute introduces a departmental principle in the central management of the Management Board, creating 7 permanent working committees. The chairmen of these commissions are elected by the Congress and are vice-chairmen of the BDA. The statute provides for the possibility of creating, if necessary, temporary working committees. Such a commission, established by decision of the Congress of the BDA, is the Expert Commission on the problems of dental care and contracting with the NHIF. By decisions of the Management Board, other temporary committees on specific problems are created.

Control authorities:

The Committee on Professional Ethics supervises the moral-ethical and deontological aspects of the practice of the dental profession. The Control Commission monitors the legality and constitutionality of the decisions of the Management Board and their implementation. BDA includes 28 regional colleges, which are independent legal entities with their own statutes. Their

leadership reproduces at the regional level the same governing bodies (General Assembly, Management Board) and control bodies (Professional Ethics Commission, Control Commission). As a member state of Europe, the Code of Ethics of the Council of European Dentists is a very important document for the Bulgarian dentist. Undoubtedly, the Code has no binding force. However, this does not mean that it should be underestimated or neglected. Its observance has enormous moral value for the dental community. Not because if it is violated, Europe will impose penalties: there is no such European body to do so. Statutory jurisdiction operates within the country in which it is practiced - whether in our country or somewhere else - and is formally subject to the regulatory requirements of that country. However, the CED Code of Ethics is a sort of Magna Charta for European dental practitioners. Examining the topic of quality in dental practice and the related consideration of the topic of "quality of dental care", the issue of the powers and activities of the Professional Ethics Commission of the Bulgarian Dental Union and the regional ones should also be considered, in the context of the role and place of these control structures in their nature in improving the quality of medical services in our country.

2.2.5. Quality of care in dental practice

The NHIF monitors the quality of dental care in the mandatory health insurance system, according to criteria agreed with the Health and Safety Executive and included in the National Framework Agreement. The Ministry of Health, through its Medical Audit Agency, audits the quality of dental care according to the current dental standards. The quality of dental care in private practice has not been actively monitored. A certain control is carried out by BDA on the basis of the Code of Ethics. Patient complaints are usually handled by the Regional and National Ethical Commissions of the BDA and the Ministry of Health, supplement EAMA/EAMS.

2.2.6. Activity of the Committee on Professional Ethics at BDA

The Committee on Professional Ethics of the regional college of the BDA consists of a chairman and members. The number of members is determined by the statutes of the organizations. The commission is guided in its work by the statute of the regional board, by the rules of procedure and by the code of professional ethics of the BDA.

The commissions have the following powers:

1. Monitor compliance with professional-medical, moral-ethical and deontological issues related to the exercise of the profession;

2. Consider complaints on the above-mentioned issues;

3. Perform other functions assigned to it by the general meeting of the district collegium of BDA;

4. Issue a report on established violations and recommendations for their removal.

Pursuant to the Law on Professional Organizations of Doctors and Dentists, violations and the sanctions provided for in the law for doctors are:

- Pursuant to Article 37 of the Law on Professional Organizations of Doctors and Dentists, doctors are liable for the following violations committed in the performance of their professional duties:

- Non-compliance with the rules stipulated in the codes of professional ethics;
- Failure to comply with the rules of good medical practice.For violations under Article 37 of the Law on Professional Organizations of Doctors and Dentists, the following penalties may be imposed:

1. Rebuke;

2. A fine in the amount of one to five minimum wages - for non-compliance with the rules provided for in the codes of professional ethics; respectively in the amount of five to ten minimum wages - for non-compliance with the rules of good medical practice;

3. Deletion from the register of the college for a period of 3 months to one year - for violations of non-compliance with the rules provided for in the codes of professional ethics; respectively, for a period of 6 months to two years - for non-compliance with the rules of good medical practice.

Violations under Article 37 are established by an act of ascertained violation. Every member of the committee on professional ethics of the regional board of the BDA has the right to draw up acts. Penal decrees are issued by the chairman of the management board of the regional board of the BDA. A copy of the criminal decree is sent to the head of the health facility where the punished person works, and to the director of the Regional Health Insurance Fund. The drafting of the acts, issuance and appeal of the criminal decrees under the Law on Professional Organizations of Doctors and Dentists is carried out in accordance with the Law on Administrative Violations and Penalties. The sums of the imposed fines go into the revenue of the regional board of the BDA. The imposition of penalties under Article 37 does not preclude seeking criminal, civil or disciplinary liability under the Labor Code. The Committee on Professional Ethics is elected by the Congress of the Bulgarian Dental Association (BDA), to which it also reports on its activities. It carries out its activities in accordance with the provisions of Bulgarian and European legislation, the Law on professional organizations of doctors and dentists, the Code of Professional Ethics of Dentists and the Statute of the BDA. The Committee on Professional Ethics of the BDA prepares and adopts regulations for its activity. The Committee on Professional Ethics of BDA consists of a chairman and 8 /eight/ members, elected by name by the Congress of BDA. The Committee on Professional Ethics of BDA meets at least once every 6 /six/ months with a quorum of 2/3 of its members, i.e. in the presence of 6 /six/ members of the Commission. When a complaint is submitted to the Professional Ethics Commission of the Health and Safety Executive, forwarded by the Ministry of Health, the Executive Agency "Medical Audit"/ EAMA, another state body or

other instance, the complaint is sent to the relevant regional board, which is competent to consider the complaint and at the same time the complainant is notified of compliance with the procedure regulated in the Statute of the BDA. The Committee on Professional Ethics of the BDA instructs the relevant Regional College of the BDA to return a decision or opinion on the given case within a reasonable period, which cannot be longer than 3 months. For the purposes of this work, data from reports on the activities of the Commission on Professional Ethics, provided by the Bulgarian Dental Association and the Sofia Regional College, are presented. From the information provided, several important points can be highlighted regarding the number of complaints received, the problems identified, expressed in the signals and complaints submitted and the results achieved in view of the powers of this kind of control body for the class of dental doctors.The data presented are for the activity of the Professional Ethics Commission for the period 2014-2017, due to the non-holding of the Congress of the BDA, given the epidemic of COVID-19 and the consequences of the imposed anti-epidemic measures. Following the activity of the Professional Ethics Commission of the BDA with mandate 2014-2017, it is established that during the past period the Professional Ethics Commission of the Bulgarian Dental Association considered 59 complaints. The data shows that the number of complaints has doubled compared to the previous three-year term, during which the number of complaints was 28.

Table.№ 1. Types of complaints

Number of complaints	Prosthetic treatment	Implantology	Surgically treatment	Therapeutic treatment	Combined	Ethical	Normative documents	Others
28	10	5	1	3	3	2	2	2

From the analysis of these complaints, the main problems that patients concern in them are:

- The bad attitude of dental doctors towards patients.
- Failure to issue a receipt for the services rendered.
- Discrepancy between expectations and the final result of the treatment.
- Allowing compromises in the treatment plan in order to provide financial relief to the patients.
- Failure to provide the declaration of informed consent and its signature by the patient.
- Non-observance of the rules of good medical practice, allowing incompetent persons to perform treatment activities in the dentist's office.
- Failure to comply with standards in dentistry.
- Violations related to the activities performed at the regional health insurance funds.

On the basis of reports received from the Regional Committees on Professional Ethics at the BDA, the largest number of complaints were received and considered in the Regional Board - Sofia, - 28. In the Plovdiv Regional College - 14 complaints and 23 cases of improper dental behavior.

The Committee on Professional Ethics at the Metropolitan Regional College has exceptionally ended its 4-year mandate due to Covid-19. The commission's activity is fully in line with the code of professional ethics of dentists, which reflect the moral principles and criteria for professional behavior of the dental profession. During the term 2017-2020, a total of 66 complaints were received and 10 complaints so far for 2021. By type, the most 16 were for prosthetic treatment, followed by therapeutic 12, orthopedic -11, implantology 7, surgical 6, orthodontics 5 and pediatric dentistry 4. The characteristics of the complaints coincide with those described above.

Table.№ 2. Types of complaints - Metropolitan Regional College

Number of complaints	Prosthetic treatment	Implantology	Surgically treatment	Therapeutic treatment	Pediatric dentistry	Orthodontics
66	24	7	6	10	4	4

For the entire mandate, 4 acts and 2 criminal decrees were drawn up

The most common errors are: lack of informed consent and incomplete medical documentation. In all conflict situations, Commission on Professional Ethics has made efforts to achieve reconciliation between the dentist and the patient, always striving to establish the objective truth in relation to the presented cases. The analysis of the complaints found the following weaknesses and outlined the general problems in the field of dentistry:

Main omissions in the treatments carried out:

- ✓ Lack of treatment plan
- ✓ Lack of registration in outpatient journal
- ✓ Lack of informed consent
- ✓ Allowing compromises in the treatment performed
- ✓ Patient dissatisfaction with treatment results

According to the code of professional ethics, article 25, paragraph 1, it is mandatory to keep complete medical documentation of the patient, according to the relevant normative order. Regardless of what was established, which to a large extent established a lack or seriously reduced quality of dental care, no administrative criminal proceedings were opened on any of the complaints and the powers of the BDA as an administrative punishing body were not implemented. Although the data, which are scarce and cannot lead to a full analysis of the problem with the implementation and, in particular, the implementation of the control functions of the Commission on Professional Ethics, one can draw an indisputable conclusion that a problem in the field of dental medicine from the point of view of efficiency and increase of quality through control is a fact.

2.2.7. Rules for Good Medical Practice of Dental Medicine Doctors in the Republic of Bulgaria

Republic of Bulgaria

The rules of good medical practice in dentistry aim to ensure the highest possible quality of patient care. They are prepared in accordance with the requirements of Article 88 of the Health Law, Article 46 of the Health Insurance Law, Article 77 of the Medical Institutions Law and Article 5 of the Law on Professional Organizations of Doctors and Dentists. They are mandatory for all dentists in the Republic of Bulgaria. The Code of Good Dental Practice offers general guidelines for all dental practitioners together with specific guidelines against which treatment performance can be assessed. The rules for good medical practice in dentistry were issued by the Minister of Health and promulgated in the State Gazette, issue 41 of 08.05.2020. The general rules include a system of guidelines and principles that describe the professional values, knowledge, skills and behavior that doctors in dentistry may apply in accordance with their experience and professional judgment. According to these rules, the dentist should: put patient care first, treat patients politely and carefully, respect their dignity and protect patient confidentiality, listen to and respect patients' position, inform patients in a way they understand, respects the right of patients to participate in decision-making regarding their treatment, develops and updates his professional knowledge and skills, is aware of the limits of his professional competence, is honest and inspires trust, does not disclose confidential information, does not allow his personal views to influence of treatment, acts promptly to protect patients from risks arising from non-compliance with the rules of good medical practice, does not take advantage of his professional position in his relations with patients, cooperates with his colleagues in the interest of patients. For dentists, good medical practice includes rules for the quality of the following activity, namely:

- putting the patient's health and interests first;
- ensuring a high standard of diagnosis and treatment;
- not to discriminate against patients except on clinical grounds (urgency);
- adequate assessment of the patient's condition, based on his medical history and clinical picture, and paraclinical examinations;
- performing or referring for performing the necessary specialized examinations for making adequate decisions;
- ensuring the implementation of clinical protocols;
- ethical communication with patients and their families;
- ensuring that complete and accurate medical records are kept;
- ensuring adequate care after completion of treatment;
- using the knowledge and skills of colleagues when necessary;

The diagnosis and treatment carried out or organized by the dentist must be based on his thorough clinical assessment of the patient's needs and the expected effectiveness of the treatment. Good dental practice includes: adequate assessment of the patient's condition; carrying out and planning

examinations and treatment when necessary; referring the patient to another dentist/physician if necessary. A dental practitioner, when he realizes that his ability to treat patients qualitatively and safely is limited (due to insufficient equipment or other reasons), should remove the cause if possible. In the event that the dentist cannot cope, he should refer to an appropriate health institution or fellow dentist. The dentist must take care to describe the treatment options clearly and comprehensively and in terminology easily understood by the patient. He should discuss with the patient all appropriate treatment options (including no treatment) and expected outcomes. With regard to children, as well as those with special needs, great attention should also be paid to effective communication with parents or guardians/custodians. Decisions about treatment options should be shared. It should be considered good practice to obtain written informed consent for any form of treatment as required by law. Having the patient sign an informed consent is not a substitute for appropriate two-way communication. The rules of good medical practice for dentists also contain a "special part" which deals with professional conduct in the diagnosis and treatment of certain dental diseases and conditions.

- ✓ Special rules for the treatment of dental caries
- ✓ Special rules for conducting endoscopic treatment
- ✓ Special rules for good medical practice in prosthetic dentistry
- ✓ Special rules for diagnosis and treatment of periodontal diseases
- ✓ Special rules for diagnosis, prevention and treatment of dento-jaw deformities and anomalies.
- ✓ Special rules of conduct for uncomplicated tooth extraction and acute odontogenic infection.

2.2.8. Joint activities - BDA as a class organization and Medical Audit Executive Agency in professional ethical relations

On March 19, 2015, the Executive Agency "Medical Audit" hosted a meeting with the representatives of the Bulgarian Dental Association, the occasion was the finalization of negotiations and the signing of a memorandum of joint cooperation - part of the agency's initiative for joint actions with trade organizations along the line "control-quality-standard" in medical activities. As a result of the signed memorandum and the priorities set by the parties, serious changes have been achieved in the provision of dental services at the national level, which generally affect the serious issues of patient safety, the protection of the attending dentist, risk management in the analysis of the activity and prevention in relation to the most frequently committed violations in the implementation of dental medical care. For the purposes of this dissertation, the data from inspections carried out in the field of dental medicine as part of outpatient medical care are also presented. As a result of received complaints, the Executive Agency "Medical Audit" carried out inspections in 24 outpatient dental clinics. The most frequently raised problems are in the area of quality, unregulated payments and moral and ethical issues. As a result of the results of the performed control activity and in connection with the signed

Memorandum of Cooperation between EAMA and BDA, as part of the institution's strategy for risk-based auditing is the development of a specialized Declaration for informed consent and its implementation in the work of dental doctors. A main problem of a deontological nature is the conditions and obligations of doctors towards their patients to inform and accordingly express the so-called "informed consent", which represents a relatively new legal figure that has become necessary in practice in view of the changed social relations related to the provision and the use of dental services in the country. In connection with a signed Memorandum of Cooperation between the Executive Agency "Medical Audit" and the Bulgarian Dental Union, a Declaration of "informed consent" was developed and adopted for the needs of the guild of dentists. The developed draft of the Declaration contains the various hypotheses laid down in the Health Law for persons expressing informed consent, as well as all other details related to the conditions for expressing informed consent. The written form of the document largely guarantees the security and safety of both the patient and his dentist when performing treatment-diagnostic medical activities. All this, as a process that ended with an achieved result in the protection of the guild, is seen as a faithful and effective managerial approach with care for the class, which is functionally and organizationally subordinate to the BDA. With what was achieved, the danger for the dentist was clarified in cases where he performs a medical intervention without informed consent, which in turn is related to taking the risks that are inherent in the respective intervention. It is these risks that, by obtaining informed consent, are transferred from the doctor (the one performing the intervention) to the patient (the one for whose benefit the intervention is being performed). In view of all the presented facts, arguments and considerations, regarding the issues related to the provision of dental medical care, the partners have adopted the opinion that the provision and, respectively, the receipt of "Informed Consent" should be in written form, which ensures that the patient , as well as his dentist.

A specialized Declaration of Informed Consent for dental medicine doctors was jointly developed by BDA, Sofia College and Executive Agency "Medical Audit" and adopted at the BDA Assembly in 2015.

Analyzes in the dental sector, prepared in cooperation between the Executive Agency "Medical Audit" and the Bulgarian Dental Union, impose an opinion on the mandatory nature of the declaration of informed consent and its written form. A similar understanding is imposed by the conclusion that local infiltration anesthesia in the sense of Article 89, paragraph 1 of the Health Act is also an "invasive method", and the legal definition of the term "invasive method" presented by the legislator in paragraph 1 point 3 of The additional regulations constitute: "Invasive methods" are diagnostic and therapeutic instrumental methods, in which the human body is penetrated by breaking the integrity of the skin and mucous membranes or through natural openings. The risks of performing a medical intervention, by obtaining informed consent, are transferred from the doctor/dentist (the one who performs the intervention) to the patient (the one for whose benefit the intervention is performed). By informing the patient of his doctor, and the short "yes" or "no" expressed by the patient regarding his dental treatment, forms the difference between wrongful

conduct and due medical conduct and care. Through the information, the patient understands that although it is aimed at improving his health, the dental medical intervention can also lead to certain adverse consequences. By agreeing to the risks described by the dentist, the patient assumes any adverse consequences objectively related to the treatment, of which he has been informed. An application finds the rule "to whom it benefits, harm to him". However, if the patient did not consent to the treatment, he did not assume the associated risks. Therefore, in these cases, the dental doctor, who did not receive informed consent, will be responsible not only for the damages that occurred as a result of a possible medical and/or medical error (culpable non-compliance with treatment standards, good medical practice, normative and sub-normative acts) , but also for the adverse consequences that occurred as a result of the eventual realization of the objective risk associated with the implementation of the medical intervention itself (intrinsic and unavoidable in the implementation of this intervention). In the absence of informed consent, the doctor assumes the risk of carrying out the treatment.

3. Executive Agency "Medical Supervision"EAMS - authority and control in dental practice

Analyzes in the sector of dental medicine prepared in cooperation between the Executive Agency "Medical Audit" Executive Agency "Medical Supervision" is the legal successor of the Executive Agency "Medical Audit" (the original name of the agency was the Executive Agency "Medical Inspectorate", but later the Law on health was amended - State Gazette No. 101/2009, in force from 01.01.2010, and the name of the agency was changed to Executive Agency "Medical Audit" (IAMO). The agency started its activity from 1 January 2010.) and from April 2019, together with the Transplantation Agency, it acquires a new name and functions IAMN. It is a legal entity of budgetary maintenance - a secondary allocator of budget credits to the Minister of Health, with its headquarters in the town of Sofia. The powers are regulated by Art. 7b of the Law on Medical Institutions, Article 11 of the Law on Transplantation of Organs, Tissues and Cells, as well as in Chapter IV of the Law on Health Insurance. and the Bulgarian Dental Union impose an opinion on the mandatory nature of the declaration of informed consent and its written form. A similar understanding is imposed by the conclusion that local infiltration anesthesia in the sense of Article 89, paragraph 1 of the Health Act is also an "invasive method", and the legal definition of the term "invasive method" presented by the legislator in paragraph 1 point 3 of The additional regulations constitute: "Invasive methods" are diagnostic and therapeutic instrumental methods, in which the human body is penetrated by breaking the integrity of the skin and mucous membranes or through natural openings. The risks of performing a medical intervention, by obtaining informed consent, are transferred from the doctor/dentist (the one who performs the intervention) to the patient (the one for whose benefit the intervention is performed). By informing the patient of his doctor, and the short "yes" or "no" expressed by the patient regarding his dental treatment, forms the difference between wrongful conduct and due medical conduct and care. Through the information, the patient understands that although it is aimed at improving his health, the dental medical intervention can also lead to certain adverse consequences. By agreeing to the risks described by the dentist, the

patient assumes any adverse consequences objectively related to the treatment, of which he has been informed. An application finds the rule "to whom it benefits, harm to him". However, if the patient did not consent to the treatment, he did not assume the associated risks. Therefore, in these cases, the dental doctor, who did not receive informed consent, will be responsible not only for the damages that occurred as a result of a possible medical and/or medical error (culpable non-compliance with treatment standards, good medical practice, normative and sub-normative acts) , but also for the adverse consequences that occurred as a result of the eventual realization of the objective risk associated with the implementation of the medical intervention itself (intrinsic and unavoidable in the implementation of this intervention). In the absence of informed consent, the doctor assumes the risk of carrying out the treatment.

3.1 Algorithm of inspections of dental practices and results

The control activity of the Agency is based on an established methodology and algorithm for checks. Checks can be carried out on site at the relevant medical facility or on documents. Currently, there is also the practice of requesting documents from the Medical Institutions by mail, in accordance with the pandemic situation.

Required documents for inspection of Medical Institutions/dental practice are regulated in the Inspection Methodology of the EAMA

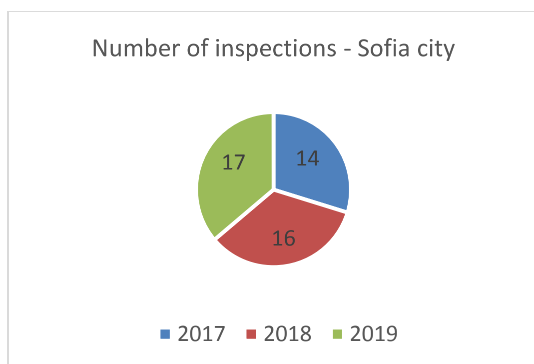
3.2. Results of the inspections carried out by EAMA/EAMS for the period 2017-2019

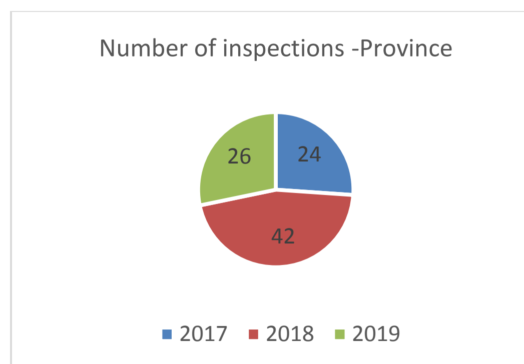
Binomial test was used to analyze the results of the performed inspections to compare the differences in the frequency of the detected violations. Violations were analyzed by type and legal act, and a comparative analysis of the inspection results between Sofia-city and province was made. Applying the above-mentioned algorithm for the period 2017-2019, a total of 139 inspections were carried out, the majority of which was 42.6% in 2018. 45 Medical Facilities were inspected in the city of Sofia, or 33% of all inspected Medical Facilities and 97 (67%) in a province.

Table.№ 3 . Inspections for 2017-2019 of EAMA/EAMS

Years	Number of checks	Valid Percent
2017	36	25,7
2018	59	42,6
2019	43	31,6
General	139	100,0

Fig.№1. Number of inspections - Sofia city **Fig.№ 2. Number of checks-Province**





In total, for the whole country, 40% of the inspected Medical Facilities are without violations, about 60% have established violations. The most are violations of the Health Act -23.9%, followed by the right of access -10.1%, medical documentation and standards. By types of violations, the following are the most: medical documentation - not filled out outpatient list - 20.1%, lack of informed consent - 17.3%, financial document not issued - 5.8%. By region, the most violations were found in Sofia city (32.4%), Plovdiv (24.5%), Varna (15.1%), Pernik (5%), the least - Kyustendil, Haskovo and Sofia region (0.7).

Violations found in the city of Sofia according to regulatory documents and by type are identical, a total of 45. In 62.2% of the inspections, no violations were found, in 13.3% the 3rd health law was violated, in 11.1% there were violations in the medical documentation , and in 6.7% the "access" regulation was again violated. Here, too, the most common finding is the lack of a completed outpatient list 17.8% and lack of informed consent 11.1%. In the provincial inspections, the most frequent violations were again the lack of informed consent - 20.2%, unlawfully paid amount for dental service 20.1% and lack of issued financial document 7.4%.

Comparison of the type of violations between Sofia and the province

Binomial test is used to compare the differences in the frequency of detected violations: during the inspections of dentists in Sofia city and province Binomial test showed that this difference is significant (62.2% without detected violations in Sofia city vs 30.1% in the province; p<0.001).

- Of the health law during the inspections of dentists in Sofia-city and the province. Binomial test showed that this difference is not random (p=0.008). Sofia city (86.7% without detected violations) and province (71%).

- ➢ Access to medical assistance during the performed inspections of dental doctors in Sofia-city and province. In Sofia-city (93.3% without established violations) and province (88.2%). Binomial test showed that this difference was not significant (p=0.14).
- ➢ Binomial test is used to compare the percentages of violated medical documentation verified colleagues in Sofia-city (89.9% without detected violations) and province (93.5%). Binomial test showed that this difference was not significant (p=0.2).
- ➢ In keeping an outpatient list, during the performed inspections of dental doctors in Sofia-city and province. In Sofia-city (82.2% without established violations) and province (78.7%). Binomial test showed that this difference was not significant (p=0.31).
- ➢ In obtaining informed consent during the performed inspections of dental doctors in Sofia-city and province. In Sofia-city (89.9% without detected violations) and province (78.8%). And Binomial test showed that this difference is significant (p=0.049).

In the comparative analysis of the results of the inspections carried out by the Ethics Commission of the BDA and EAMA/EAMS, identical findings were found: the most violations are lack of informed consent and incomplete medical documentation:

- ✓ Lack of treatment plan
- ✓ Lack of registration in outpatient journal
- ✓ Allowing compromises in the treatment performed

The results again support the opinion on the mandatory nature of the declaration of informed consent and its written form. The danger for dentists, both in general and dental medicine, in cases where they perform a medical intervention without expressed informed consent, is related to the assumption of the risks inherent in the respective intervention. The dentist, who has not received informed consent, will be responsible for the damages that occurred as a result of a possible medical and/or medical error (culpable non-compliance with treatment standards, good medical practice, normative and sub-normative acts). In the absence of informed consent, the doctor assumes the risk of carrying out the treatment.

3.3. Questionnaire survey “Risk Management“. Results and discussion

The survey "Risk management" in dental practices aims to improve the quality of dental care. The specific tasks are to establish:

• The danger for the dentist in cases where he performs medical intervention without informed consent

• Need for joint cooperation between the Executive Agency "Medical Supervision" and the Bulgarian Dental Union

• Prevention of complications, errors and accidents

• Ensuring the safety and security of both the patient and the dentist

The results of this study provide better insight into the quality of dental care, attitudes towards the quality of dental health care, as well as respect for the rights and interests of dental practitioners, as well as patient satisfaction with the health care received. 128 dentists were surveyed for a period of 10 months (02. 20219-10.2019). There are 16 questions asked. About 90% responded positively to the first question, which indicates a good awareness of the importance of this element of quality.

Fig. № 4. Compliance with safety rules

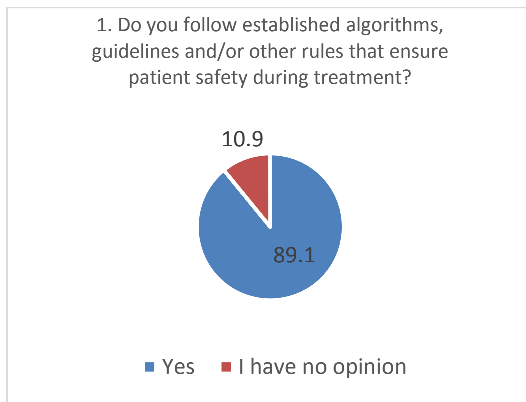
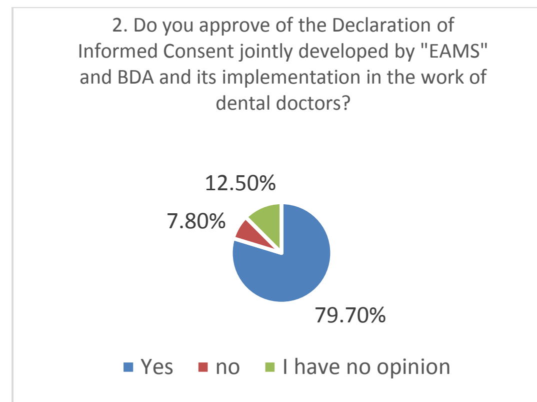
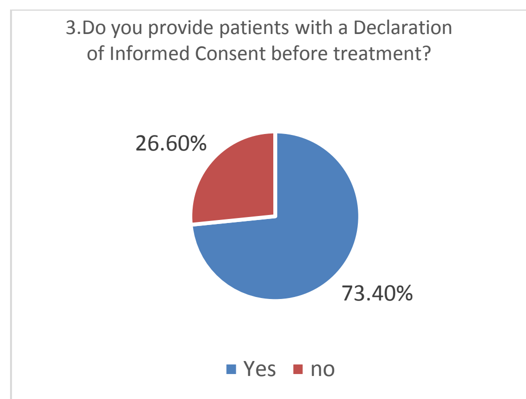


Fig. № 5. Approval/disapproval



Here the interpretation of this answer is interesting (Fig. 5), about 20% do not have an opinion or disagree, which does not correspond to the answer about safety (Fig. 4), where 90% agree that security and safety are an important factor for the quality of the service. Rather, this answer says that dental doctors are not convinced of the importance of informed consent to protect against the assumed risk in carrying out the treatment. This is also confirmed by the fact that 26.6% (fig. 5) do not provide it before treatment.

Fig. № 6. Provision before treatment to patients Declaration of informed consent



The two related questions of whether it is explained in accessible language what can be expected from the treatment and whether the content of the declaration is comprehensible have divergent answers. Almost all 98.4% (fig. 7) answered that the communication between doctor and patient was carried out and at the same time 18% (fig. 8) considered that they did not explain the content of the declaration comprehensibly. Whether this is due to disapproval of the content of the declaration itself or the reluctance on the part of the dentist to spend more time explaining is difficult to answer.

Fig. № 7. Is it explained in accessible language?

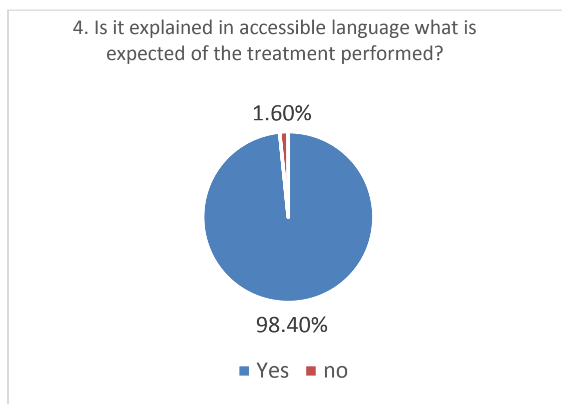
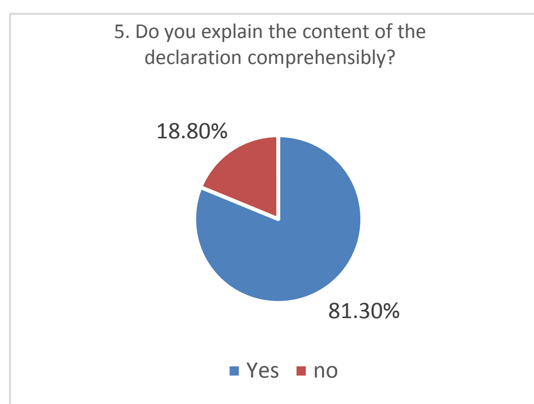


Fig. № 8. Are you explaining clearly?



The remaining 11 questions deal with the attitude of dental practitioners to medical errors and malpractice, the prevention of their admission, the need for an information system for registration and discussions on these problems. Both the WHO classification and reports from other countries working on the issue of patient safety primarily present definitions of "medical error" as the result of weaknesses in management. There are no definitions of 'medical malpractice', but there are definitions of 'negligence': 'Lack of care or diligence and/or failure to carry out one's duties' (Australian Council for Quality and Safety in Health Care, 2001) or 'Failure to skill, care or knowledge of the healthcare provider is applied" (WHO, 2009). In 2009, after two years of research, the Global Alliance for Safer Health Care at the WHO published its Technical Report on the International Classification of Patient Safety. This classification contains definitions of 297 terms in the field. Legal definitions from Bulgarian sources for "medical error" can be found in the monographs of (S. Slavov, 1990) (R. Ilkova, 2010), (Radanov, 2004), Petrova, . doctor, carried out under optimally created working conditions, as a result of ignorance or underestimation of the circumstances and/or the condition of the patient, in which adverse consequences for his health and life occurred, but could have been prevented" (Petrova Z. EAMA, "Medical error", 2010).

In many cases, the error is due to the intervention of various factors:

• patient characteristics – seriousness of the disease, communication problems (foreigner), other personal and social factors;

• factors resulting from the nature of the work itself – availability and use of protocols, availability of research results, accuracy of results;

• factors arising from the individual characteristics of the doctor/nurse – knowledge, skills and competence, fatigue, motivation, physical and mental health;

• factors resulting from teamwork - communication during the provision of medical care in routine and crisis conditions, monitoring and seeking help, leadership;

• factors resulting from working conditions – workload, availability and use of equipment, administrative support;

• factors resulting from work organization and management – financial resources, time, physical environment (lack of space, noise level, etc.). (Petrova Zl. 2011, 2014).

The issue of medical errors is seen as an opportunity to distinguish a practice-acceptable omission from a socially dangerous activity. (Radoinova, 2013). The detection and analysis of medical errors is a much bigger and more serious problem than that of medical errors, because it means making a change in order to improve the organization and management of processes in medical facilities. This change requires time, patience and the involvement of all staff. To question No. 6, are you aware of the danger for the dentist in cases where he performs medical intervention without informed consent, 96.9% gave a positive answer, which confirms the thesis that a dentist who has not received informed consent, will be responsible for the damages that occurred as a result of a possible medical and/or medical error (culpable non-compliance with treatment standards, good medical practice, normative and sub-normative acts).

Fig. №9. Danger in the absence of inf. consent

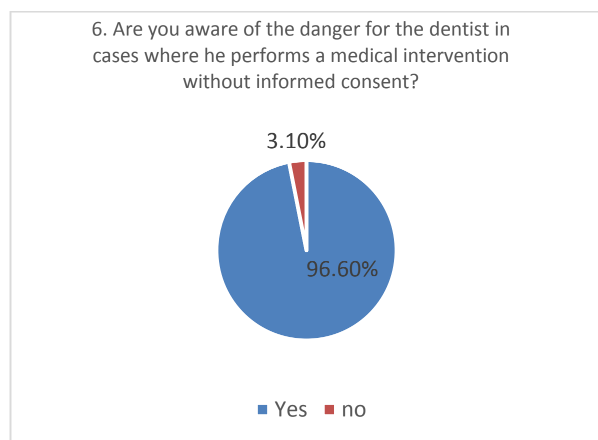
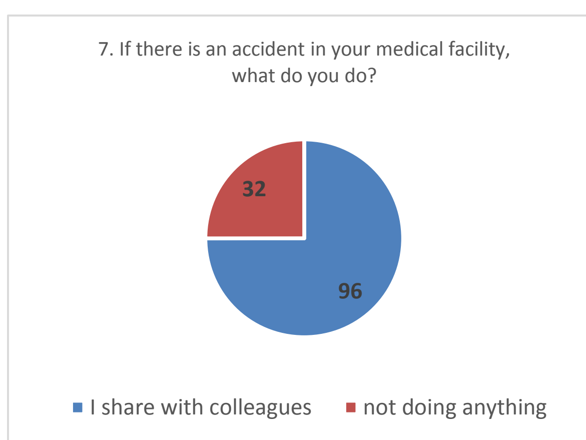


Fig. №10. If there was an accident?



Almost ¼ of respondents say they avoid commenting, while 75% share and discuss with colleagues. Practically, this means that a large part do not share because they are afraid of legal prosecution and sanctions. The seventh question concerns the creation of a database for the processing and prevention of complications, errors and incidents. About 16% are not convinced

that it is necessary, and 88% consider that holding discussions is also necessary. Preventing future errors and improving patient safety requires using a systems approach to address the root cause of these errors. Applying this approach means that attention should be directed not so much to the search for "who is to blame", but "what and why this happened". No one is at risk of making mistakes that "can be made even by the best specialist or in the best organization." The aim is not to make accusations and impose punishments, but to learn from mistakes and prevent them from being repeated, i.e. it is necessary to go from continuous disapproval to continuous improvement of the processes in a given medical facility.

Fig. №11. Creating database

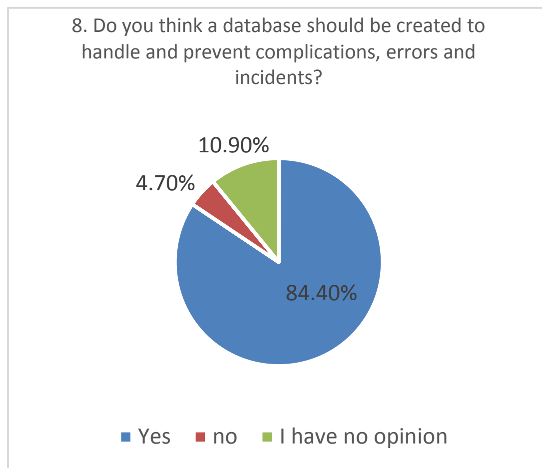
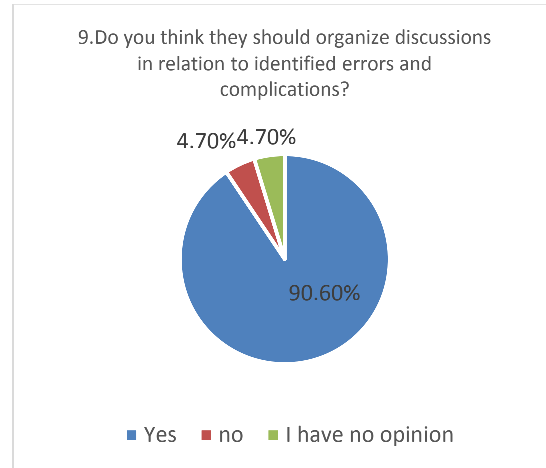


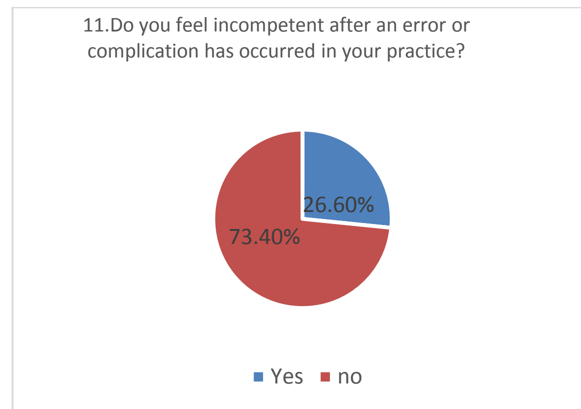
Fig. №12. Organizing discussions



The answers to questions #10, 11, 12 outline the professional attitude of dental doctors towards possible mistakes and omissions, the comments, communication with the patient when explaining the mistakes made. Of the respondents, ¼ are worried about comments about mistakes made and feel incompetent, and 70% are worried about how to explain their admission to patients.

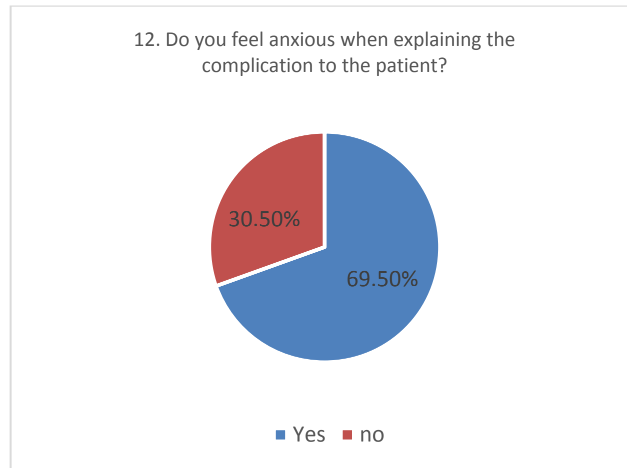
Fig. №13 Worried about commenting?

Fig. №14. Competencies



There is broad agreement in Western Europe and the American Medical Association on the ethics of errors. That the "damaging" mistake should be acknowledged, the patient should be informed, the patient should understand and decide on his subsequent behavior. Research shows that most patients want to know about potential risks and errors, and disclosing them improves the relationship with the doctor. The patient understands that there is a mistake, but wants to know the moment when it happened.

Fig. №15. Status when explaining the errors made



Sometimes the doctor decides in the best interest of the patient not to be informed, but most patients are willing to participate in this decision. The patient-doctor relationship is based on confidentiality and trust. Although the patient is a passive recipient of care from the doctor who decides what is good and what is not and whether to be informed, most patients nevertheless want to participate in decision-making about their health. Error detection is also related to patient knowledge. Through disclosure and discussion, the physician minimizes the outcome of the injury. Doctors should explain the circumstances surrounding the error in non-medical, clear, honest and understandable language. Before disclosing the error, the doctor should clarify all the facts, details and circumstances and reveal the full realistic picture leading to the potential future harm. Immediate disclosure of the error is the best approach. Full disclosure of even minimal errors improves the relationship, the atmosphere of dialogue, facilitates the patient's participation in making a medical decision about his health. . It is the responsibility of everyone working in the health care system to support the "victims" of errors, and it is everyone's ethical duty to support their disclosure. That is why we want to raise the culture and study medical errors.

The last four questions concern the dentists' evaluation of the safety conditions in the health care facility, the partnership between the health care center and the control institution, as well as the informed consent as a tool ensuring the safety of both sides of the diagnostic treatment process - dentist/patient. Between 75 and 80% of this cooperation meets the approval of dental practitioners and as a result the creation of the Informed Consent Model for Invasive Dentistry.

Fig. №16. Assessment of safety conditions

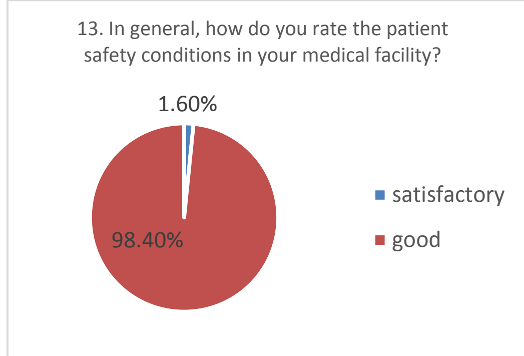


Fig. №17. Evaluation of the signed Memorandum

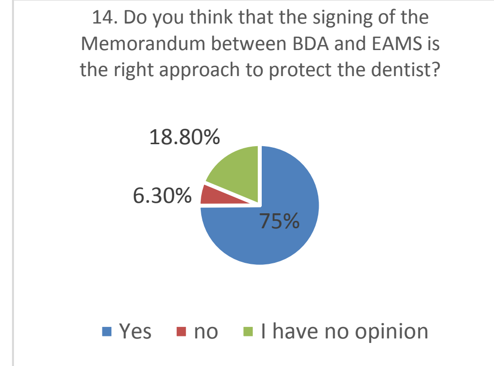


Fig. №18. EAMS-BDA partnership approval

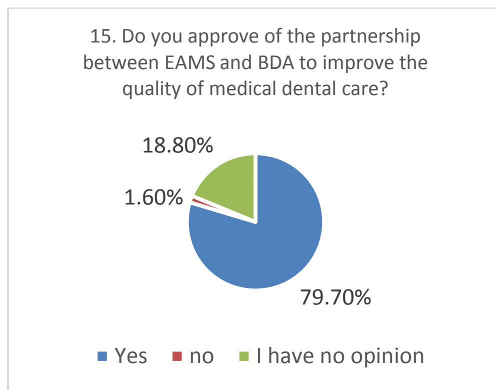
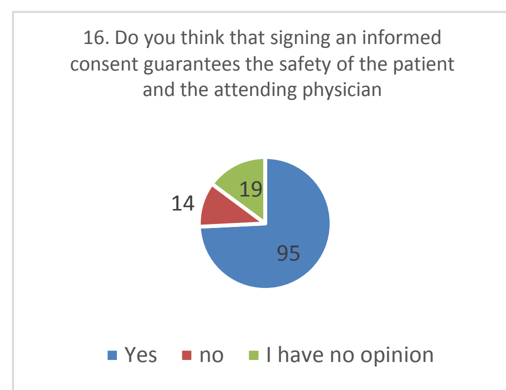


Fig. №19. Informed consent and security



Internal consistency was examined using Cronbach's α. Values above 0.70 are considered satisfactory. Cronbach's α. for the conducted survey it is 0.86. Internal consistency was examined using Cronbach's α. Values >0.70 were considered satisfactory Cronbach's α for all 36 items was 0.86. After analyzing the results, conclusions and recommendations will be made that could contribute to guaranteeing the safety and security of both the patient and his dentist in the performance of treatment-diagnostic medical activities contributing to the prevention of complications, errors and accidents at work.

4. CONCLUSIONS AND RECOMMENDATIONS

4.1. Conclusions from the literature review

1. Quality indicators underpin the development of standards as a fundamental element of quality measurement. A metric/indicator is a measure of actual system performance that indicates the degree to which desired results are achieved or the degree to which manuals and standard operating procedures are adhered to.

2. The monitoring system as a step in the quality assurance process is a system for periodic collection and analysis of data on selected indicators that allow to assess whether the key activities have been carried out according to the preliminary plan and whether they have the expected effect on the target population.

2. Quality assurance is a complex of activities for establishing standards, for monitoring and improving medical services in order to achieve the most efficient and safe service possible.

5. The standards ensure that the reasonable limit of price-quality-efficiency relations will not be exceeded. The standards guarantee that the patient will be treated in medical facilities with specialists, policies and equipment that meet modern requirements and in a manner that meets good medical practice while respecting his basic human rights.

6. The role of the audit is to support clinical and business decisions, taking into account the services that are provided, the risk and the management of the activities. Through the audit, decisions are made on how unsatisfactory results can be improved after corresponding positive changes and how strengths can be promoted and perceived by others.

7. Risk management and quality improvement systems are aimed at providing a structural framework for the identification, analysis, treatment/corrective action, monitoring and review of risks, problems and/or other opportunities.

8. Risk-based approach (RBP) means an approach in which the competent authority and the obliged entities identify, assess and understand the risks related to the quality of medical care to which the assessed entities are exposed, and take measures that are proportionate to these risks.

9. A complex of dentist, practice, and patient factors influence the service delivery process in addition to oral status. Professional dental factors such as choice of treatment modality, practice beliefs, patient preferences, and demographic characteristics influence service patterns.

10. There is scope for clinical outcomes research in general dental practice to improve knowledge through medical records that are accurate, comprehensive and timely, on the basis of which treatment decisions are made and which identify potential problems and offer adequate advice and care.

11. Dental care organizations represent the fastest growing segment in oral health care. The goals of the organizations are to standardize the health care provided to patients by reducing non-clinical burdens on practitioners.

12. There are quantitative and qualitative indicators for the evaluation of conventional and surgical activities in general dental treatment.

13. In modern deontological medical care, the obtaining of the patient's consent is a prerequisite that transforms the impact on the human body from a criminal offense into a treatment, from a

socially dangerous behavior into a legally regulated profession containing a serious risk that is taken with in view of the achievement of a higher public goal - the preservation and restoration of human health

14. Informed consent as a process - a part of the treatment process in which each patient must receive high-quality, timely, truthful, understandable and sufficient information about: his diagnosis, possible treatment options and their risks, and express his disagreement / consent to carry out the proposed treatment.

15. The informed consent as a document - a means of evidence for the circumstances reflected in it and declarations of will regarding: the patient's state of health at a given time, the reasons for the treatment, the possible options and risks of not/carrying out the treatment, the patient's consent or refusal to undergo overall treatment or a specific procedure.

4. 2. Conclusions from an analysis of dental practices in European countries and dental practice in Bulgaria

1. The NHIF monitors the quality of dental care in the system of compulsory health insurance, according to criteria agreed with the Health and Safety Executive and included in the National Framework Agreement. The Ministry of Health, through its Medical Audit Agency, audits the quality of dental care according to the current dental standards. The quality of dental care in private practice has not been actively monitored.

2. A certain control is carried out by BDA on the basis of the Code of Ethics. The drafting of the acts, the issuance and appeal of the criminal decrees under the ZSOLLDM is carried out according to the ZANN. The judicial practice in this type of case is extremely scarce, and so far there are two court decisions that overturned the criminal decrees. In their analysis, it is striking that the court's conclusions are in the direction of a lack of specifics when describing the violations

4. The most common and basic omissions in the treatments:

• Absence of a treatment plan, of registration in an outpatient journal, of informed consent

• Allowing compromises in the treatment performed

• Dissatisfaction on the part of the patient with the results of the treatment

5. It can be indisputably concluded that the problem of verbal control is a problem in the field of dental medicine.

6. Good dental practice includes: adequate assessment of the patient's condition; carrying out and planning examinations and treatment when necessary; referring the patient to another dentist/physician if necessary.

4.3. Conclusions from the analysis of the results of the inspections carried out by EAMA/EAMS for the period 2017-2019.

1. Binomial test was used to analyze the results of the performed inspections to compare the differences in the frequency of the detected violations. Violations were analyzed by type and legal act, and a comparative analysis of the inspection results between Sofia-city and province was made.

2. Applying the above algorithm for the period 2017-2019, a total of 139 inspections were carried out, the majority of which was 42.6% in 2018. In the city of Sofia, 45 Medical Facilities were inspected, or 33% of all inspected Medical Facilities and 97 (67%) in province.

3 In total for the entire country, 40% of the checked Medical Facilities are free of violations, about 60% have established violations. The most are the violations of the Law on Health - 23.9%, followed by the right of access - 10.1% and medical documentation and standards.

4. By type of violations, the following are: - not filled out outpatient list - 20.1%, lack of informed consent - 17.3%, financial document not issued - 5.8%.

5. By region, the most violations were found in Sofia city (32.4%), Plovdiv (24.5%), Varna (15.1%), Pernik (5%), the least - Kyustendil, Haskovo and Sofia area (0,7).

6. The following omissions were found in complaints and prosecutor's checks for fatal outcome: the most frequent reasons are related to lack of clinical examination and risk assessment during general anesthesia, consultation with a specialist and complication after manipulation.

7. Comparison of the type of violations between Sofia and the province. Binomial test is used to compare the differences in the frequency of detected violations: during the inspections of dental doctors in Sofia-city and province Binomial test showed that this difference is significant (62.2% without detected violations in Sofia city vs 30.1% in the province; $p<0.001$).

8. During the comparative analysis of the results of the inspections carried out by the Ethics Commission of the BDA and **E**AMA/EAMS, identical findings were found: the most violations are:

- Lack of informed consent and incomplete medical documentation;
- Lack of treatment plan;
- Lack of registration in an outpatient journal;
- Allowing compromises in the treatment performed.

9. The dentist, who did not receive informed consent, will be responsible for the damages that occurred as a result of a possible medical and/or medical error (culpable failure to comply with treatment standards, good medical practice, normative and subnormative acts). In the absence of informed consent, the doctor assumes the risk of carrying out the treatment.

4.4 Findings from the survey „Risk Management”

1. The survey "Risk Management" was conducted among 128 dental doctors for the period 02.2019-10.2019. There were 16 questions, grouped into 4 groups:

- the danger for the dentist in cases where he performs medical intervention without informed consent
- the need for joint cooperation between the Executive Agency "Medical Supervision" and the Bulgarian Dental Association
- prevention of complications, errors and accidents
- ensuring the safety and security of both the patient and the dentist

2. To the first question, whether the established rules and algorithms that guarantee patient safety are followed, 90% answered in the affirmative.

3. The interpretation of the question about the need for "Informed consent, jointly developed by BDA and EAMS. About 23% do not have an opinion or disagree, which does not correspond to the answer about safety, where 90% agree that safety and security are an important factor in the quality of service. Rather, this answer says that dental doctors are not convinced of the importance of informed consent to protect against the assumed risk in carrying out the treatment. This is also confirmed by the fact that 26.6% do not provide it before treatment.

4. The two related questions of whether it is explained in an accessible language what can be expected from the treatment and whether the content of the declaration is comprehensible, there is a discrepancy in the answers. Almost all 98.4% answered that the communication between doctor and patient was carried out and at the same time 18% considered that they did not explain the content of the declaration comprehensibly. Whether this is due to disapproval of the content of the declaration itself or the reluctance on the part of the dentist to spend more time explaining is difficult to answer.

5. Question №6 Are you aware of the danger for the dentist in cases where he performs medical intervention without informed consent? A positive answer was given by 96.9%, which confirms the thesis that a dental doctor who has not received informed consent from the patient will be responsible for the damages that occurred as a result of a possible medical and/or medical error (culpable non-compliance with treatment standards, good medical practice, normative and sub-normative acts).

6. The seventh question concerns the creation of a database for the processing and prevention of complications, errors and incidents. About 16% are not convinced that it is necessary, and 88% consider that holding discussions is also necessary.

7. The patient-doctor relationship is based on confidentiality and trust. Although the patient is a passive recipient of care from the doctor who decides what is good and what is not and whether to be informed, most patients nevertheless want to participate in decision-making about their health.

8. The answers to questions No. 10, 11, 12 outline the professional attitude of dental doctors towards possible mistakes and omissions, the comments, communication with the patient when explaining the mistakes made. Of the respondents, ¼ are worried about comments about mistakes made and feel incompetent, and 70% are worried about how to explain their admission to patients. The answer is almost the same as to whether they comment and share with colleagues or other persons in case of possible problems or mistakes. Almost ¼ of the respondents answer that they avoid commenting, while 75% share and discuss with colleagues. Practically, this means that a large number do not share because they fear prosecution and sanctions.

10. The last three questions concern the dentists' assessment of the safety conditions in the Treatment Facilities, the partnership between the Health and Safety and Control Institution and the informed consent as a tool ensuring the safety of both sides of the diagnostic treatment process - dentist/patient. Between 75 and 80% of this cooperation meets the approval of dental practitioners and as a result the creation of the Informed Consent Model for Invasive Dentistry.

11. Internal consistency was examined using Cronbach's α. Values above 0.70 are considered satisfactory. Cronbach's α. for the conducted survey it is 0.86. Internal consistency was examined using Cronbach's α. Values >0.70 were considered satisfactory

5. CONCLUSION AND RECOMMENDATIONS

5.1 Recommendations

To the class organization of dental doctors and scientific societies:

Development of reliable and reproducible criteria for measurement and quality control, as well as a system for their tracking in dental practice.

Developing and updating rules for good dental practice. The aim is to ensure that the patient will be in the hands of qualified specialists and will be treated in medical facilities with policies and equipment that meet modern requirements and in a manner consistent with good medical practice. His basic human rights will not be violated and the reasonable limit of price-quality-efficiency relations will not be exceeded.

To the Ministry of Health, Committee on Professional Ethics at BDA:

Reviewing complaints at national level and incorporating the results into practice bulletins, with the aim of applying the lessons learned from the failures across the country. All relevant institutions should be fully engaged in this effort to ensure not just evaluation and analysis of closed cases, but real quality improvement.

Continuation of the partnership m/u BDA and the control institution for monitoring the safety conditions in the Treatment Facility, as well as the informed consent as a tool ensuring the security of both sides of the diagnostic treatment process - dentist/patient.

To the Medical Universities and BDA (continuing education and qualification).

Create a culture of safety in dental practice by including patient safety education at all levels of education as a requirement for initial and continuing certification—from medical education, through graduate training and qualification programs, and culminating in demonstrating both an understanding and of practicing the safest medicine.

5.2 Conclusion

Dental health is an essential part of the general state of health of every person, which explains and necessitates the creation and existence of a specific system of rules regarding the quality of dental care. Under the conditions of dynamic changes in health care, the basis of the health reform is the free dental practice, which contains all the basic health and support activities characteristic of dental care. The health activities of dental medicine are aimed at the treatment of dental diseases, which by their nature, complexity and complexity include medical and diagnostic measures to satisfy the dental care sought by the population, which prevents the occurrence of new dental and general diseases, as well as interaction with other subsystems in health care and beyond, in providing complex dental health. In all forms of free practice, the dentist bears moral, administrative, civil and criminal responsibility, as well as responsibility to the professional organization - Bulgarian Dental Association (BDA). Good dental practice includes: adequate assessment of the patient's condition; carrying out and planning examinations and treatment when necessary; referring the patient to another dentist/physician if necessary. The role of the audit is to support clinical and business decisions, taking into account the services that are provided, the risk and the management of the activities. Through the audit, decisions are made on how unsatisfactory results can be improved after corresponding positive changes and how strengths can be promoted and perceived by others.

6. Contribution

1. A large-scale analysis of literature sources in the field of the quality of dental services, as well as the complex of factors depending on the dental doctor, practice and patient, which influence the process of service provision, was made.
2. For the first time, a comprehensive review of the state and development of dental practices in European countries and dental practice in Bulgaria is being made.
3. Professional dental factors such as: choice of treatment method, practice beliefs, patient preferences and demographic characteristics are found to influence service patterns

4. For the first time, specialized monitoring was carried out in dental medical care, through the cooperation between the Executive Agency "Medical Audit" and BDA.
5. The specialized monitoring and supervision in dental medical care works in the direction of increasing and confirming the prestige of dental medicine doctors, good medical practice and patient safety.
6. Through an analysis of the "Risk Management" survey conducted in dental practices, the need to assess the dental doctors for the safety conditions in the Medical Facilities, the partnership between the BDA and the control institution, as well as the informed consent as a tool ensuring the security of both parties is proven of the diagnostic treatment process-dental doctor/patient, in order to improve the quality of dental care.
7. Reliable and reproducible criteria for measurement and quality control have been developed, as well as a system for their follow-up in the dental practice.
8. The role of audit in dental practices has been proven to support clinical and business decisions by considering the services being provided through analysis of dental records, complaints and risk assessment.
9. Risk management and quality improvement systems provide a structural framework for the identification, analysis, treatment/corrective action, monitoring and review of risks, problems and/or other opportunities.
10. The most frequent omissions in the diagnosis and treatment of patients with dental problems as a result of the inspections of the **E**AMA/EAMS and the Ethics Committees of the BDA have been identified and analyzed. The most frequent omissions and mistakes made in dental practice have been identified and analyzed.
11. It is emphasized that the patient's consent is central to the issues of medical care.

List of publications related to the dissertation

1. 1. Dr. Rumen Iliev, Elisaveta Petrova-Geretto, Informed consent as an element of risk management in dental practices - Journal of General Medicine, 24, 2022, No. 2, pp. 13-19.
2. 2. Dr. Rumen Iliev, "Dental practices in European countries - characteristics, registration and quality of care - review", Medical Review magazine, 58, 2022, No. 3, pp. 17-30.

3. 3. Iliev, R., R. Kolarov, E. Petrova Jeretto, Z. Petrova, "Criteria for assessing quality in dental practices and rules for good medical practice", collection of reports, jubilee scientific conference, "Man, society, medicine ", Karzhali, 2022, pp. 206-217, ISBN 978-954-652-037-1
4. 4. Rumen Iliev, "Teeth whitening - gentle and minimally invasive technique in aesthetic dentistry", "Health Policy and Management" magazine, volume 19, 4 issue, 2019, ISSN 1313-4981
5. 5. T. Cherkezov, R. Iliev, El. Petrova-Geretto, "Role of the manager in the motivation of the staff", Medical Meridians, vol. 1, 2021, pp. 10-18, ISSN-1314-1090
6. 6. Mirazchiiski B., E. Petrova-Geretto, R. Iliev, "Risk assessment of the quality of medical care in the Emergency and Surgical Department of UMBAL Burgas", magazine "Health Policy and Management", 2021 issue 2 , pp.22-29, ISSN-1313-4981