Forensic Medical Examination of the Quality of Medical Care: Legal, Methodological and Ethical Issues

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Abstract--- Qualified medical care is a fundamental component of the social policy of any civilized state in which a person, his life and health are recognized as the highest indisputable value and a special object of legal protection. Qualified medical care is the most important, but not the only segment of activity in the field of health care, because this assistance must be, first of all, timely, as well as quality at all levels: from examination, diagnosis and treatment, performing purely medical manipulations – to care, rehabilitation and restoration of vital functions, provided by the efforts of nurses. Poor or untimely medical care can lead to irreversible consequences for the patient: the transition of the disease to a chronic form, disability and even death. At the same time, it should be recognized that there may be situations in which, for objective or subjective reasons, even with the proper provision of medical care and services of the same name, it is not possible to cure, and sometimes to save the patient. A person whose health has deteriorated, and persons who have lost loved ones and loved ones because of an incurable disease, it is difficult to accept their situation, to realize that doctors have done everything they could, but medicine in such a situation was powerless. Unwillingness to objectively assess the situation often leads to an appeal to various state bodies (departmental, judicial and law enforcement) with a request to investigate the event, certainly to find and punish the perpetrators. One of the effective scientific and practical ways of objective resolution of such disputes is a medical examination of the quality of medical care.

Keywords--- Medical Care, Medical Service, Examination of Quality of Medical Care, Expert, Treatment, Patient, Patient, Doctor, Medical Staff, Negligence, Causing Death by Negligence, Causing Harm to Health, Medical History, Initiation of Criminal Proceedings, Criminal Proceedings, Civil Proceedings, Responsibility, Business Reputation, Competence, Moral Aspects, Victim, Victim.

I. INTRODUCTION

The purpose of this article is focused on the study and analysis of theoretical, organizational, methodological and (no less important) legal aspects of forensic medical examination on the quality of medical care. Special attention is
paid to the examination, which is carried out at the stage of verification measures on the fact of filing an application for bringing a doctor or other medical worker to criminal responsibility for negligent injury or death to a patient, negligence, as well as at the stage of preliminary investigation and judicial consideration of cases of the designated category. The desire of the legislator to certify the expertise on the quality of medical care as a legal category is aimed at establishing the truth in each dispute resolved with its help: bringing to justice the really guilty person and protecting the honor, good name and professional (business) reputation of a doctor or other medical worker, unreasonably accused of committing an official offense or crime.

The methodology of the study of phenomena and processes of medical activity, the results of which are reflected in this work, is presented by dialectical, comparative-legal, modeling and prognostic methods. The result of this work has been a number of recommendations of the legal, moral, ethical and methodological plan aimed at radical improvement of the procedure of departmental and judicial review of materials and criminal cases on charges of poor quality of medical care with the mandatory use of data obtained in the course of specialized expert research. The authors' findings are objective and complex, since they are equally aimed at satisfying the reasonable claims and requirements of the applicants and protecting the business reputation of medical workers who are unjustly and unreasonably accused of violating the legislation on health protection and protection of patients' rights. The complex nature of the study is manifested in the situational analysis of events related to the accusation of poor quality of medical care from the standpoint of medical (including corporate) ethics and deontology.

The implementation of the proposed recommendations in the judicial practice and activities for the provision of medical care can play a significant role in the creation of a legal regime that ensures objectivity and impartiality of the consideration of disputes about the nature and quality of medical care and services with the use of expert research.

The program provision of social and legal policy of any modern civilized state is the care of a person, his life, health, decent existence. The health of the population, the increase in the birth rate and life expectancy of people are indicators that reflect the well-being and effectiveness of the social policy of the state. But such an aspiration makes special demands on medical activity in any of its forms-the provision of medical care or similar services.

The famous Greek healer Hippocrates, who lived about 460 BC, in the text of his well-known oath bequeathed to his disciples and followers: "Treat the patient so that you want to be treated to you. Above all, do not harm." (Apforifmi Hippocratis. Juxta. Optimam Editionem. 1689). By reciting the words of this oath before entering upon an independent professional career, doctors commit themselves to devote their lives to the greatest mission-the treatment and healing of people.

The achievements of modern science have long overcome the brink of the impossible in medical activity-diagnoses, voiced earlier as a verdict or fatal inevitability, are now understood as a setting for choosing the right treatment method. At the same time, it should be recognized that the most advanced developments in any field of human activity in the process of their practical application are influenced by the human factor. There is no exception in the medical sphere, in which this factor has a "bilateral" manifestation, combining the professional activities of a doctor or nursing staff, who are entrusted with the care of the patient and carrying out current medical procedures.
(nursing), and the behavior of the patient, as well as his age, health, in short, individual physiological ability to resist the disease.

World practice knows many cases when due to objective or subjective reasons, even with proper and timely medical care to cure, and sometimes save the life of the patient fails. A person whose health has deteriorated, and persons who have lost loved ones due to an incurable disease, it is difficult to accept their situation, to realize that doctors have done everything they could, but medicine in such a situation was powerless. The inability, and in some cases outright unwillingness to objectively assess the situation entails an appeal to various state bodies (departmental, judicial and law enforcement) with a request to investigate the event, to give it an "objective" assessment, to find and severely punish the perpetrators.

The requirement of objectivity in assessing situations associated with an unfavorable outcome of treatment dictates the need to recognize the "downside", that is, that poorly provided medical care can lead to irreversible consequences: the transition of the disease into a chronic form, disability and even death of the patient.

No one case of adverse outcome of treatment should not remain without due attention of the medical community (both scientific and practitioners): such situations should be discussed at various levels (from a workshop in the office of the head of the Department or in the office of the chief physician of the hospital to regional and Federal health authorities). In particularly complex and resonant cases, such issues can become the subject of attention of the medical community on a global scale.

The best methods to treat not the disease, and the patient can be developed and put into practice only with this approach. At the same time, one of the most effective scientific, practical and legal ways to objectively resolve such disputes is medical expertise on the quality of medical care.

II. LEGAL BASIS OF FORENSIC MEDICAL EXAMINATION ON THE QUALITY OF MEDICAL CARE.

Questions and Discussions

The task of protecting the health of the population, including through the provision of qualified and, equally important, timely medical care, dictates the need to create an optimal, responsive to the needs of practice, a viable mechanism that ensures the use of all available resources in the health sector in accordance with the program of state guarantees.

The international code of medical ethics (adopted in October 1949 in Geneva, Switzerland; amended: in August 1968 at the 22nd world Medical Assembly, held in Sydney, Australia; in October 1983 at the 35th world Medical Assembly, held in Venice, Italy) establishes the rule that, in making professional decisions, the physician must proceed from considerations of good for the patient. It is noteworthy that a similar requirement—the priority of the patient's interests in the provision of medical care is specified in the Federal law of November 21, 2011. "About bases of protection of health of citizens in the Russian Federation". (Federal Law of the Russian Federation of 21.11.2011 № 323-FL "on the basis of health protection of citizens in the Russian Federation" (amended from 03.08.2018) (hereinafter – FL № 323) // Rossiyskaya Gazeta № 263, 23.11.2011). Such a sense of medical activity
means its focus on a favorable result, but in any event, the correctness of the prescribed treatment can be evaluated by appropriate expert research.

Expertise is a form of using special knowledge of a special knowledgeable person (expert), providing information through specialized research (deductive knowledge). (Grishina E. P. Theoretical and legal mechanism of the use of special knowledge in Russian criminal proceedings in the context of its purpose and adversarial principles. Moscow: Yurlitinform, 2016. P. 195).

Issues related to the examination of the quality of medical care are becoming increasingly relevant and of scientific and practical importance. And this is not surprising, since they "concern without exception all medical organizations directly providing this assistance, and, therefore, have a direct relationship to citizens seeking medical care" (Piven D. V., Kitsul I. S., Ivanov I. V. The order of examination of the quality of medical care / / Health Manager. 2016. № 6. P. 6). Expert research is a legal concept based on a set of provisions contained in normative documents of various levels. They regulate, on the one hand, the right of citizens to health care, qualified medical and legal assistance, and on the other – establish the procedure for the appointment and examination of the quality of medical care in criminal and civil proceedings.

The Constitution of the Russian Federation, adopted by popular vote on December 12, 1993, enshrined the right of everyone to health care and medical care (Article 41), to state protection of human rights and freedoms (Article 45), as well as the opportunity to familiarize themselves with documents and materials directly affecting their rights and freedoms, unless otherwise provided by law (part 2 of article 24). (Constitution of the Russian Federation adopted by popular vote 12.12.1993 (amended from 21.07.2014). Assembly of the legislation of the Russian Federation. 04.08.2014. № 31. 4398). These constitutional provisions are equally relevant to the protection of the rights of patients and the protection of honor, dignity, business reputation of doctors and other medical professionals. In the latter case - in the situation of unjustified charges of negligence, causing death by negligence or medical error, formally not a crime, but can entail liability established by the norms of civil law.

The unfounded accusation of a doctor or a representative of the nursing staff in an irresponsible attitude to their duties, incompetence or negligence in each individual case should be evaluated critically. With the approach of a different kind of professional career of these persons can significantly suffer, not to mention the fact that worthy representatives of medicine can leave this path, unable to cope with moral suffering and humiliation, as well as the distrust of their colleagues. In any case, the assessment should be legal.

FL № 323 in the Article 64 "Examination of quality of medical care" establishes that the examination is conducted in order to identify irregularities in the delivery of health care, including assessing the timeliness of its rendering, the correct choice of methods of prevention, diagnosis, treatment and rehabilitation, degree of achievement of planned result. Criteria for assessing the quality of medical care are formed by groups of diseases or conditions based on appropriate procedures for providing medical care and clinical recommendations (treatment protocols) on the provision of medical care. Examination of the quality of medical care provided within the framework of compulsory medical insurance programs is carried out in accordance with the legislation of the Russian Federation on compulsory medical insurance.
The main normative legal act, the prescriptions of which are used in the examination of the quality of medical care, is the Federal Law of 29 November 2010 № 326 "on compulsory medical insurance in the Russian Federation" (Federal Law of 29.11.2010 № 326 "on compulsory medical insurance in the Russian Federation" amended on 29.07.2018 // Rossiyskaya Gazeta. № 274, 03.12.2010).

Examination of quality of medical care, except for care provided in accordance with the legislation of the Russian Federation on compulsory medical insurance, is carried out in the procedure established by the authorized Federal body of Executive power.

A specialized normative legal act regulating all types of expert activity is the Federal Law of 31 May 2001 "On state forensic expert activity in the Russian Federation". (Federal Law of 31.05.2001 "On state forensic activities in the Russian Federation" (as amended on 08.03.2015) // Rossiyskaya Gazeta № 106, 05.06.2001). This law establishes that the task of the state forensic expert activity is to assist courts, judges, bodies of inquiry, persons conducting an inquiry, investigators in establishing the circumstances to be proved in a particular case, by resolving issues requiring special knowledge in the field of science, technology, art or craft (Article 2).


The criminal procedure code provides for the appointment of expertise and obtaining expert opinion, starting from the stage of verification of the message about the crime (part 1 of the Article 144). Such a legislative establishment allows a timely decision to initiate a criminal case in the presence of an act (action or omission) of a medical worker signs of a crime, and to refuse to initiate a criminal case in the presence of circumstances precluding criminal liability. In this case, it is not excluded the possibility of providing interested parties with a conclusion of non-judicial examination, followed by a study of it as another document provided for in the Article 84 of the code of criminal procedure, a specialist.

No less justified from the methodological and legal sides is currently recognized thesis about the justification of the use in the appointment and examination of the expert opinion, including if it is provided by the defense or the victims (Grishina E. p. Conceptual and legal problems of the use of special knowledge in criminal proceedings of Russia: monograph. Moscow: Yuriltinform, 2018. Pp. 237).

Appointment and production of forensic medical examination to establish the causes of death, as well as the nature and extent of harm caused to health, based on paragraphs "a"," b" part 1 of the Article 196 of the criminal procedure code, in criminal proceedings is mandatory. Consequently, this requirement applies to criminal prosecution of persons accused of causing death or injury to the patient by negligence. As for the examination on the quality of medical care carried out in the framework of civil proceedings, its findings may serve as a basis for the appeal of a doctor or other medical professional for judicial protection of honor, dignity and business reputation in

The specialized branch normative document regulating questions concerning quality of medical care is the Order of the Ministry of health of Russia" About the approval of criteria of an assessment of quality of medical care " of Bay 10, 2017.

№ 203 n (further – the Order № 203n) (the Order of the Ministry of health of Russia "about the approval of criteria of an assessment of quality of medical care" of 10.05.2017 № 203 n // [Electronic resource]. Official Internet portal of legal information. URL: http://www.pravo.gov.ru). This order establishes the main criteria for the quality of medical care (which can be considered and analyzed in the course of the eponymous expert study) in outpatient settings (paragraph 2.1), in inpatient conditions and in a day hospital (paragraph 2.2), as well as criteria for the quality of medical care for groups of diseases (Section III).

A positive role in the expert assessment of the quality of medical care could be played by the system of so-called quality improvement programs developed and implemented in medical practice, containing a list, a clear structure and sequence of measures aimed at protecting the health of the population, taking into account climatic conditions, the environmental situation, the organization of the health care system in certain regions.

The above-mentioned programs are currently focused on assessing the quality of treatment of diseases of a certain type, for example, cardiovascular, cancer, which significantly limits the rights of patients and complicates the process of assessing the professional activities of doctors, especially in the situation of growth of diseases of a certain type or an increase in the mortality rate of patients (both have complex etiology and need objective expert justification).

Examination of quality of medical services based on specialized programs as well as normative legal acts and departmental regulations adopted with the participation of professionals and members of public organizations specializing on protection of the rights of patients who are able to provide "the possibility of obtaining objective, reliable and timely data on the processes that make up medical care, conditions of its provision, the efficient use of resources, and the level of result after its rendering" (Seregina I. F., Knyazev E. G., small M. G., Taewsky B. V. examination of quality of medical care in modern conditions // Vestnik Roszdravnadzor. 2016 № 1. P. 16).

III. SCIENTIFIC AND METHODOLOGICAL BASES AND ETHICAL ASPECTS OF MEDICAL CARE QUALITY EXPERTISE

Dialectical, comparative-legal, content-analytical methods have actively been involved in the study of the issues of appointment and production of examination of the quality of medical care. The conducted research, in turn, allowed to formulate a number of recommendations and conclusions of the methodological and ethical plan concerning appointment, the organization and production of examination of quality of rendering medical care (or services, in case of need of their assessment). Production of expertise on the quality of medical care should be carried out in strict accordance not only with legal regulations, but also with the scientific and methodological foundations of expert activity in the field of medicine. The following points should be taken into account:
• The presence of a complaint, appeal or statement of the patient or his representative, legal representative, relatives or close persons;

• The presence of an explanation of a doctor or other medical professional whose professional activity is the subject of expert research.

In the absence of such an explanation, the expert study will be incomplete, biased and unjustified from the standpoint of medical ethics and deontology;

• Availability of Grounds for Examination

The procedural basis for the examination in the framework of verification activities carried out in accordance with part 1 of the Article 144 of the code of criminal procedure is the decision of the investigator, and when considering a civil case in court-a court ruling or a judge's decision in accordance with the Article 79 of the Civil procedure code of the Russian Federation.

Some difficulties when making decisions on the appointment of expert studies is the lack of a categorical indication in the law as to what a particular species should be carried out it is judicial-medical examination in the framework of verification of the facts of improper medical assistance with a fatal outcome of the patient prior to the initiation of criminal proceedings (Nesterov A. V., Kirik V., Ivankin M. P. Quality of manufacture is judicial-medical examination for improper provision of medical care fatal // far Eastern medical journal. 2018 № 2. Pp. 77);

• Availability and Sufficiency of Materials (objects, documents) for Expert Research

The last requirement is one way to eradicate noted National medical chamber of the Russian Federation "traditional" negative attitude of physicians to the quality of medical records, since the evaluation of quality of care based on the principle of proper management of medical documents (Kovynev I. B. Quality of care in the field of gemology in a large industrial center of Western Siberia // Wschodnioeuropeiske naukowe. 2018. № 2-1. P. 52).

To conduct an expert study on the quality of medical care at the disposal of the expert may be provided: case history; the document of giving informed voluntary consent to medical intervention or refusal of medical intervention. The form of this document was approved by Order of Ministry of health of the Russian Federation of 20 December 20012, № 1177 n (order of the Ministry of health of the Russian Federation of 20.12.2012 № 1177 n "On approval of the procedure of giving informed voluntary consent to medical intervention and refusal of medical intervention with respect to certain types of medical interventions, forms of informed voluntary consent to medical intervention and refusal of medical intervention" // the Russian newspaper № 145, 05.07.2013);

• Clinical summary;

• Outpatient card;

• The act of medical consultation and the medical Commission issued according to requirements of the Article 48 of the Federal Law "About bases of protection of health of citizens in the Russian Federation»;

• The act of pathological-anatomical autopsy of the corpse;

• Conclusion of the forensic medical examination on the nature and severity of harm to health caused to the patient, or the cause (s) of his death;
• Explanations or indications (in the latter case – in the presence of the initiated criminal case) of victims (the patient or his relatives in case of death of the patient), witnesses;
• Materials of official and departmental inspections;
• Departmental instruction;
• Samples of labor contracts providing functional duties of medical workers;
• Copies of civil contracts for the provision of medical services;
• Licenses granting the right to carry out medical activities and provision of medical services;
• Copies of documents confirming the presence or absence of drugs and equipment necessary for emergency care and treatment of the patient;
• References, written consultations and expert opinions (e.g. medical history);
  *availability of General guidelines (guidelines) to assess the quality of medical care and services;
  *availability of the completed certificate-table “quality criteria for groups of diseases (conditions)”, filled in accordance with the instructions contained in the Order № 203 n.

Representatives of medical science and practitioners suggested the advisability of issuing additional but key document card examination, which must be made of the results obtained in the course of expert studies of quality of care related to timeliness of delivery, the correct choice of methods of prevention, diagnosis, treatment and rehabilitation, degree of achievement of the planned result (Breskina).

T.N. The card of examination of quality of medical care as a basis of the organization of quality control of medical care in a multidisciplinary hospital / / Vestnik Roszdravnadzor. 2016 № 1. Pp. 21-22). It is believed that the examination card is necessary to assess the quality of the medical institution, the formation of generalized statistical data for reporting and when considering individual complaints of patients who are dissatisfied with the results of treatment or have claims relating to the quality of medical services provided. Such a map is not so effective for use in conducting verification activities to address the issue of criminal proceedings and judicial review of criminal or civil cases.

In case of insufficient material for study, the expert may submit a written refusal report (in particular, in criminal proceedings, a similar procedure provided for in paragraph 6 of part 2 of article 57 of the criminal procedure code of the Russian Federation), the expert has no right to collect materials for expert examination (item 2 of paragraph 4 of the Article 57 of the Criminal Procedure Code of the Russian Federation).

The problem segment of legal regulation of examination of quality of medical care is the absence of a rule establishing safety requirements and justification (of course, evaluation criteria) of this assistance, as well as the justification of risk in the individual medical procedures (open heart massage or some techniques used in emergency obstetric care, etc.). It seems that these rules should be developed and legalized in the near future, since in their absence it is impossible to talk about the presence of the required methodological and legal basis for the examination of the type in question. In particularly complex cases, the examination of the quality of medical care should be comprehensive (in the production of which experts of different specialties participate) or Commission (conducted by at least two experts of the same specialty). Compliance with such organizational and methodological
recommendations is necessary to protect a conscientious doctor or a representative of the nursing staff from unfounded accusations of negligence to their professional duties, incompetence; violation of the rules of medical ethics and deontology, expressed in inattentive, squeamish or cynical attitude to the patient (for example, being in a state of drug or alcohol intoxication, unconscious, untidy, etc.), especially if these actions are assessed as having caused the death of the patient.

The requirement of objectivity and an integrated approach in the expert study on the quality of medical care in the legal context follows from the prescription contained in part 3 of the Article 17 of the Constitution of the Russian Federation that the exercise of human and civil rights and freedoms should not violate the rights and freedoms of others. The right of a patient, his or her legal representatives or relatives to claim that the medical care provided is substandard is "balanced" and legally consistent with the right of any medical professional to an impartial investigation of the circumstances set out in the complaint and to protect his or her professional reputation. In short, the legal field is the same for all.

In medical institutions, especially stationary type, such experience of an assessment of quality of the rendered medical care and the relation to patients as the book of responses which pages are sewn manually is widely used and are necessarily numbered (in order to avoid removal). In addition, on the websites of hospitals, polyclinics, hospitals, dispensaries, hospices there is a special section "Reviews". In specialized departmental bodies and departments of health practice "hotlines" with multi-channel phones, which can call any citizen and Express their opinion on the quality of medical care provided, for example, in a hospital in General or a doctor – in particular.

Information obtained through the involvement of sociological tools that reflect the satisfaction or dissatisfaction of the population with quality medical care or the services (of Redjucov A.V. the Study of public opinion on satisfaction by medical care quality of municipal urban district // the Bulletin of national research Institute of public health named after N. And. Semashko. 2012 № 4. P. 122), generalized and systematized can also be used for the formation of the expert's conclusions. In this case, the findings may relate to the activities of the medical institution, and a employee. Such an approach is justified both from the standpoint of the methodology of sociological research and from the standpoint of compliance with ethical standards in professional medical activity.

The reality is that a responsible, competent and attentive doctor can be "accused" by a patient of indifference and unprofessionalism. At the same time, more than a dozen citizens expressed their gratitude to this doctor. The conclusion is – maybe the requirements and dissatisfaction of the patient is not entirely justified and reflect the characteristics of his character or nervous system disorders resulting from the disease, or just two people did not find a common language?

Summarizing the above, it can be argued that the results of examinations of quality of medical services and related sociological research "provide an opportunity to obtain reliable and structured information about the medical processes at the level of medical institutions, thereby providing the ability to timely identify negative aspects of its activities, the use of means for their elimination and the development of measures on increase of efficiency of activities by providing quality and affordable medical care" (Shvets Yu. Yu. Problematic aspects of the examination of the quality of medical care // Guide entrepreneur. 2016 № 32. Pp. 241).
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V. SUMMARY

1. Expertise on the quality of medical care is a complex concept based on a significant arsenal of normative legal documents, involving the following of certain scientific and methodological recommendations and ethical standards. The uniqueness of this expertise lies in the fact that its results—the conclusions contained in the conclusion of the expert (or experts) can be used to make legally significant decisions in the framework of criminal or criminal procedure law, and when making decisions in civil proceedings.

2. Examination of the quality of medical care is not only an effective way to protect the rights of patients affected by the negligence and incompetence of doctors, but also a means of protecting the honor, dignity, business reputation of the latter in the case of unfounded accusations.

3. From a financial point of view, the results of examination of quality of medical aid can serve as a legal basis for going to court with a claim for compensation in a situation of causing harm to health or death of the patient (in the latter case, the claim may be filed by its relatives), and equally to justify the amount of financial compensation for harm caused by unfounded accusations made to the medical provider.

4. Based on the conclusion of the specified examination within the criminal procedure law the decision on initiation of criminal case or on refusal in initiation of criminal case is made, and production on criminal case is carried out.

5. Examination of quality of medical aid is an essential tool for assessing activities of medical institutions in general and specific doctor or even representative of the average medical personnel (midwives, feldshers, nurses) in particular.

6. Examination of the quality of care as an additional component should assess the safety and the degree of justification for the use of specific medical manipulations.

7. Active involvement of expertise on the quality of medical care can play a significant role in the protection of health and ensuring the viability of citizens.

8. Complex legal Institute of medical care quality expertise can have a positive impact on the development of health care in the country, visibly improve the quality of medical care and related services.

9. The importance of the examination carried out on the quality of medical care dictates the need to transform its methodological and improve the legal framework.

Firstly, to develop criteria for assessing the quality of medical care, sociological data contained in reviews and other communications of citizens should be more actively used. The legal basis of the examination should be based not only on Federal legislation, but also on departmental acts aimed at providing medical care to patients living in certain regions of Russia. Expert research should assess not only the quality of medical care, but also the quality of medical services provided (in the latter case, negative results of the examination can serve as a basis for revoking the license).
The requirement of objectivity of the expert opinion and expansion of prospects of use of its results in law enforcement and medical activity dictates urgent need of legislative expansion of the list of documents and materials provided to the expert (experts) for research.

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Articles
