

SECTION 8. THEORETICAL MEDICINE

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8.1 Conceptual principles for reforming the quality management system of medical care in Ukraine

High-quality medical care is a service for which resources are organized in such a way as to meet the needs of those who need help as efficiently and safely as possible, to carry out prevention and treatment without unnecessary costs, in accordance with the requirements and possibilities of the modern level of scientific development.

In the recommendations of the European Regional Office of the WHO, during the formation of the quality management system of medical care, four main components should be taken into account: qualification of a doctor; optimal use of resources; risk for patients; patient satisfaction with the provided medical care.

The quality system of medical care provision is multi-component, which can be classified in two directions. The first direction: structure quality and process quality. The second direction: objective quality component (technical quality) and subjective component (patient's perception) [298].

The quality of the structure is a component of the quality of medical care that describes the conditions of its provision.

The quality of the structure is determined by two levels:

Level 1: the level of the health care institution as a whole with its material and technical base, staffing, work organization, service conditions. The conditions for providing medical care at the institution can be assessed by the medical and preventive institution itself, the health care management body, and entities paying for the provided medical services. The most complete assessment is carried out in the process of licensing and accreditation of health care institutions.

Level 2: the level of each medical worker of the institution, where the professional qualities of the doctor are evaluated. The evaluation procedure is reduced to the passing of exams and credits after completion of the appropriate form of postgraduate training, as well as certification of medical personnel [299].

The quality of technology is a component of the quality of medical care that describes the process of providing medical care. The quality of technology determines the algorithm of providing medical care from the moment of diagnosis to the end of treatment and characterizes the optimal complex of medical and diagnostic measures for a specific patient. At the same time, it is assumed that the volume of performed manipulations should be neither less nor more than optimal, and the sequence of their execution is strictly observed. If more funds were spent on the treatment of the patient than necessary, such assistance will not be of high quality, even if good treatment results are achieved.

The quality of the technology is evaluated only on one level - in relation to a specific patient, taking into account the clinical diagnosis, types of accompanying pathology, the age of the patient and other biological factors.

One of the parameters characterizing the quality of technology can be the presence or absence of medical errors.

The quality of the result is a component of the quality of medical care that describes the result of the provision of medical care (the ratio of the actually achieved results to the planned ones).

Depending on the evaluated object, planned results mean: dynamics of a specific patient's health; the results of treatment of all patients in a medical and preventive institution for the reporting period; the state of health of the population of the territory.

Therefore, the quality of the result can be evaluated on three levels:

Level 1 – the level of a specific patient. It is estimated to what extent the achieved results of the treatment of this patient are close to the possible results of his treatment, taking into account the clinical diagnosis, age, etc.

Level 2 – the level of all patients who visited a health care facility for any period (usually a year). In the practice of medical institutions, many aspects are used that characterize the quality of the treatment result. A special place among them is occupied by: mortality, postoperative mortality, frequency of postoperative complications.

Level 3 – the level of medical care for the population. This level of assessment of the quality of the result is characterized by indicators of population health (morbidity, mortality, infant mortality, birth rate, etc.).

In many European countries, the concept of the quality of medical services is considered as a set of the following indicators: efficiency; economy; adequacy.

Efficiency is understood as the ratio of the actually obtained result to the result that could be obtained under ideal conditions [299].

Economy is understood as the ratio of real costs to the standard cost.

The criterion of adequacy is the ratio between the provided medical care and the medical care that the patient needs. Such a criterion consists of several concepts:

1. The scientific and technical level of using modern medical knowledge and technologies in the medical and diagnostic process.

2. Timeliness - the ratio between the time of providing medical care and the time of the need for a certain service before the provision of a medical service and the need, if the system were to work under ideal conditions.

3. Availability of medical care – the ratio between the number of people who received medical care and the number of people who needed medical care.

4. Sufficiency - the minimum consumer basket of medical services, sufficient for high-quality and adequate medical care, which does not reduce its effectiveness.

The World Health Organization (2004) proposed the following areas of quality management [300]:

1. Policy: strategy, vision and government involvement in quality improvement.

2. Organization: effective mechanisms for the implementation of national policy within the authorities at all levels with defined tasks and functions of the health care system.

3. Methodology: provision of effective methodical approaches to quality improvement, its continuous development at the state and local levels, taking into account national and international experience, scientific evidence.

4. Resources: responsibility for resourcing the quality program, which will primarily ensure the optimal level of knowledge, skills and information necessary for quality improvement.

Therefore, the creation of a quality system of medical care has the following aspects:

- political, related to the determination of priorities and decision-making in the field of regulatory and legal regulation, resource provision and implementation of public administration;
- social, related to meeting the expectations of the population and aspirations of medical workers;
- organizational, related to the improvement of management in medical institutions, development of quality systems, standardization, metrological support.

The main program document aimed at reforming the process of managing the quality of medical care in Ukraine is the "Concept of managing the quality of medical care in the field of health care in Ukraine" [301].

The main directions of reforming the management of the quality of medical care in Ukraine are presented in Fig. 1.

One of the main directions of improving the quality of medical care is the implementation of measures to ensure the availability of medical care. Quality of medical care - providing medical care and carrying out other measures regarding the organization of the provision of medical care by health care institutions in accordance with standards in the field of health care.

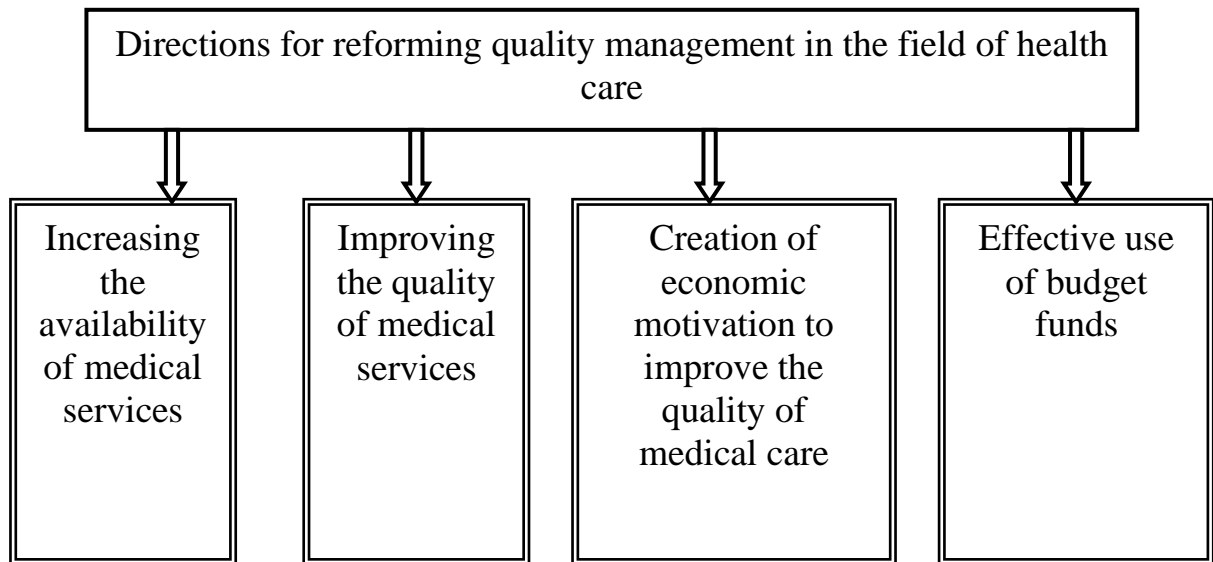


Fig. 1. Directions of reforming the quality management system in the field of health care

Availability of medical care is a real possibility for the population to receive necessary medical care, regardless of social status, level of wealth and place of residence. The main measures to increase the availability of medical care are presented in Fig. 2.

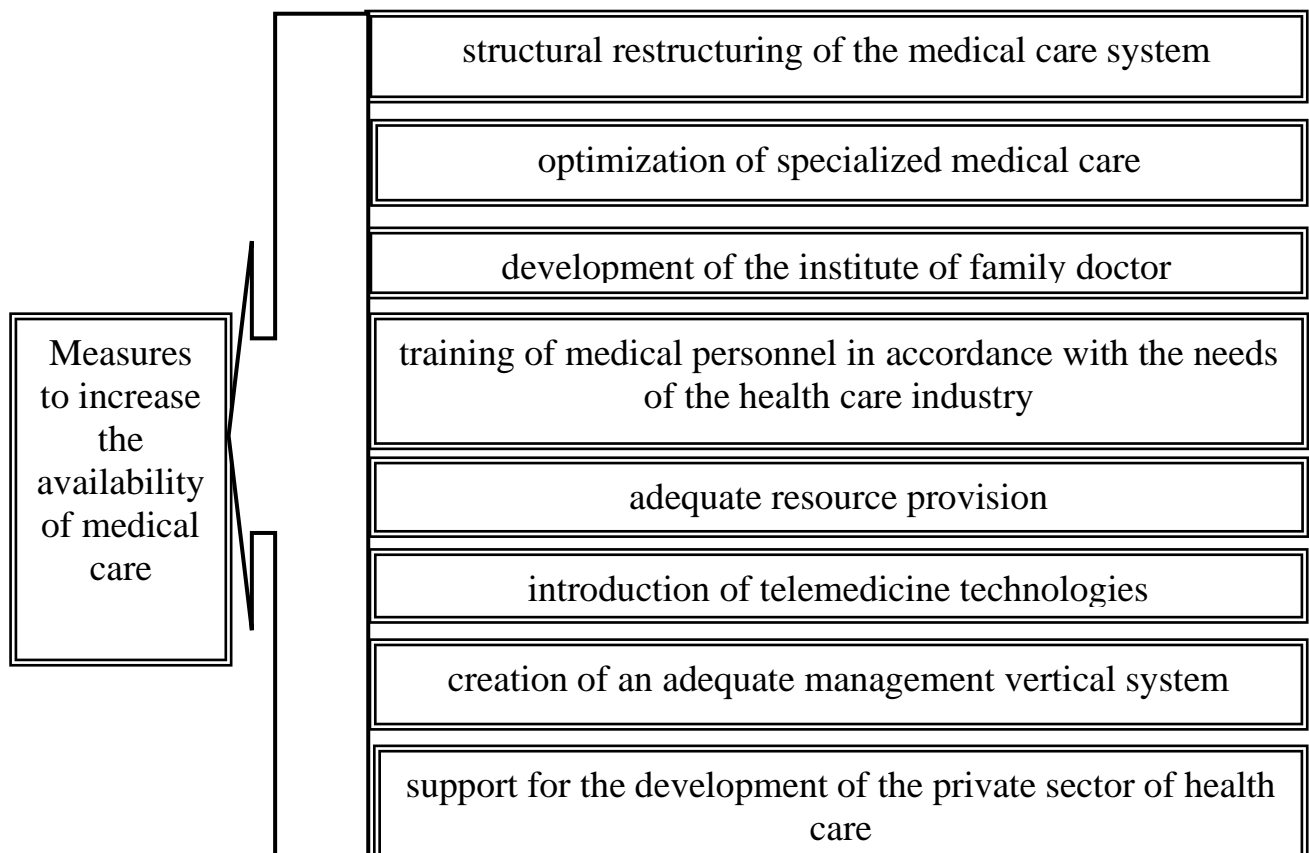


Fig. 2 Measures to increase the availability of medical care

Analysis of scientific publications devoted to quality management of medical institutions allows us to identify six main factors of quality management. Namely: organizational culture, design, quality leadership, physician participation, quality structure and technical competence [302]. Organizational culture referred to as bureaucracy type, cultural type, degree of employee empowerment [303-304], and design factors referred to as strategic approach [304], size and ownership, customer focus, and problem solving paradigm [302,304].

Measures to improve the quality of medical services should include the following elements: implementation of a contractual method of payment for medical care provided; improvement of material and technical support of treatment and prevention institutions; implementation of a system of work quality indicators; improvement of licensing and accreditation criteria; introduction of innovative technologies for providing medical care; creation of a management accounting system; introduction of information technologies for the formation of databases and processing of clinical, medical-statistical and economic information [299,305].

All component qualities are interconnected and influence each other. With a low level of quality of the structure, it is quite difficult to ensure the appropriate level of technology quality. Violation of diagnostic and treatment technology often leads to unfavorable treatment results. A high level of structure quality is only a potential, but not always realized opportunity to have a high level of technology and result quality. Such interdependence is defined as the "principle of negativity".

The mechanism for ensuring the quality of medical care unites components that ensure the quality of medical care and service to patients of health care institutions, the quality of goods and equipment.

The mechanisms for managing the quality of medical care include: standardization; accreditation; licensing; certification.

The purpose of health care standardization is to increase the quality of preventive and curative and diagnostic measures, to solve the problems of preserving and improving the health of the population.

The Ministry of Health of Ukraine has developed the Industry Standardization Program for medical care for the period until 2020, which defines the main objects and principles of standardization [306].

Objects of standardization in health care: organizational technologies; medical services; medical technologies (technologies of performing medical services); technical provision of medical services; quality (effectiveness) of medical services; staff qualification; medical supply; accounting and reporting documentation; Information Technology; economic aspects in medicine; sanitary regime requirements.

The industry standardization program in health care requires the development of the following groups of documents:

GROUP 1 - General provisions;

GROUP 2 - Requirements for organizational technologies in health care;

GROUP 3 - Requirements for technical equipment of healthcare institutions;

GROUP 4 - Personnel requirements;

GROUP 5 - Requirements for medical supplies;

GROUP 6 - Sanitary and hygienic control methods;

GROUP 7 - Requirements for medical equipment and medical products;

GROUP 8 - Requirements for dietary nutrition;

GROUP 9 - Classification and systematization of types of medical care and medical services;

GROUP 10 - Requirements for the evaluation of the treatment-diagnostic and prophylactic capabilities of medical institutions and treatment-prophylactic institutions;

GROUP 11 - Requirements for the provision of medical assistance and medical services;

GROUP 12 - Requirements for the prevention of diseases, protection of public health from factors that prevent the protection of reproductive health, and provision of medical assistance;

GROUP 13 - Requirements for the quality of medical services;

GROUP 14 - Requirements for economic indicators in health care;

GROUP 15 - Requirements for documentation in health care;

GROUP 16 - Requirements for information provision or use of information technologies.

The specified groups of requirements cover and directly affect various aspects of the organization of medical care. They are not final in the system of standardization in health care and can be supplemented as necessary with new groups.

The standardization system is developed on the basis of the general classification structure of standardization objects, contains a set of documents united by common classification features and functional purpose: clinical recommendations; standards; clinical protocols; drug formularies; classifiers ; regulations. The documents that will be used in the standards of the health care system will have a national level.

The presence of an accreditation certificate in a health care institution determines its professional level and should be the basis for concluding an agreement with an insurance company in the future.

In many countries of the world, accreditation is carried out by special commissions, which invite for this purpose well-known state experts in one or another field of activity of medical and preventive institutions. Employees of the accreditation organization and invited experts work directly with the materials of medical and preventive institutions according to specially developed programs both during the period of preparation for accreditation and during its implementation. In the future, the results of the evaluations of all experts are summarized and a conclusion is made about the compliance of this medical and preventive institution with the current standards [307].

A fundamental aspect of the success of the entire accreditation procedure is the standardization of methodological approaches to the evaluation of various medical and preventive facilities, for which interested parties contribute to the development of general, unified standards and performance criteria that guarantee high quality medical care. All health care institutions are subject to accreditation (regardless of the form of ownership).

In Ukraine, the accreditation of health care institutions is carried out in accordance with the "Standards of accreditation of health care institutions", approved by the Order of the Ministry of Health of Ukraine dated 03.14.2011 No. 142 [308].

Accreditation standards for health care facilities are requirements for the process, conditions and results of health care in a health care facility. Based on the Standards of Accreditation of Health Care Institutions, an examination of the institution's compliance with the established criteria is carried out by assessing the achievement of standards for each item/ sub item, which is carried out on a point basis. Standards that correspond to the institution's profile and the type of medical and preventive care provided by the institution are subject to evaluation.

The results of the assessment are included in the expert opinion on the institution's compliance with accreditation standards.

The institution's lack of a license for medical practice and a certificate of attestation of clinical-diagnostic and other measuring laboratories (if they exist in the structure of the institution) makes it impossible to carry out an examination of the institution's compliance with the established Criteria and its further accreditation.

Examination of the compliance of a health care institution is carried out on the basis of criteria - indicators that are calculated as a percentage as a ratio of the amount collected by the institution to the maximum possible number of points during the assessment of the achievement of standards. According to the selected percentage criterion, the relevant accreditation commission makes a decision on the qualification category of the institution (second, first, higher) or on its rejection.

The reason for refusing the state accreditation of a health care institution is its failure to reach the level of the safety index (the minimum level of the state accreditation criterion, which determines the possibility of further activity of the institution), which is 69% of the criterion inclusively.

Extraordinary accreditation can be carried out at the initiative of a medical institution in order to increase the category, but not earlier than one year after the previous accreditation. Accreditation of an institution that was denied accreditation is carried out in the same manner [299, 309].

A component of the quality management system can be considered clinical audit. The National Institute for Health and Clinical Excellence (NICE) published the paper *Principles for Best Practice in Clinical Audit* [310] which defines clinical audit as "a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery."

The main principle of the entire clinical audit process is that it should lead to the improvement of clinical practice with improved patient outcomes. It carries out a systematic critical review of the quality of clinical practice by a multidisciplinary team. With the help of a clinical audit, it is possible to track the processes of diagnosis, treatment and care of patients, the resources used and the impact of care on the outcome and quality of life of the patient.

The audit compares actual practice with standards of medical practice. As a result of this comparison, any deficiencies in existing practice can be identified and eliminated.

Clinical audit is a quality improvement process that aims to improve patient care and outcomes through:

- systematic review of care against detailed criteria derived from guidelines or clinical standards bulletins;
- implementing changes where assistance or results do not meet the expected level of re-auditing to ensure support for the changes.

Clinical audit aims to improve the processes and outcomes of patient care by systematically reviewing components of care against defined criteria and implementing changes where care or outcomes fall short of expectations. The component structures of the process and result of medical care are selected and systematically evaluated. Necessary changes are implemented at the individual, team, or institutional levels of health care delivery [311].

The legislation of Ukraine provides for monitoring the implementation of state social standards in the field of health care. Monitoring is a purposeful activity to study the state of implementation of state social standards and their financial support. Monitoring as a type of management action includes a set of measures: study of the functioning of management facilities (health care facilities) by individual types of activity; implementation of state social standards; prevention of deviations from the expected results—the scope of fulfilling the requirements of social standards by the health care institutions of the republic [307].

The purpose of monitoring the quality of medical care is to ensure the rights of patients to receive medical care in the required amount and of the appropriate quality through the optimal use of personnel and material and technical resources of health care, the use of advanced medical technologies.

The object of control is medical care (a complex of preventive, therapeutic, diagnostic and rehabilitation measures that were carried out according to a certain technology and with the aim of achieving specific results).

Quality control of medical care is ensured by a combination of its two forms: external and internal control.

External control of the quality of medical care is control of compliance with state requirements for the quality of medical care.

Current external control is a control aimed at determining the degree of conformity of activities and specific results the work of health care institutions in accordance with the state requirements of medical standards, regulations and clinical protocols of medical care.

External control of the quality of medical care is carried out by: scheduled and unscheduled inspections of compliance with licensing conditions for medical practice; expert assessment of compliance with the criteria for state accreditation of health care institutions; attestations of doctors and junior medical specialists.