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CURRICULUM

BASIC CONCEPTS OF QUALITY MANAGEMENT

Chisinau, 2025

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I. PRELIMINARY

In a constantly changing professional context, quality is an essential element of institutional performance. The course unit *Basic Concepts of Quality Management* provides the theoretical and practical basis necessary for the formation of a quality culture and for active participation in the processes of monitoring, evaluation and continuous improvement. The course unit is relevant for all specialties and qualifications, contributing to the preparation of medical specialists capable of applying quality standards, procedures and tools in their daily work.

This course unit provides the theoretical basis necessary to understand the concepts of quality, quality control, quality assurance and continuous improvement. By studying the principles and components of quality management systems, trainees acquire the ability to understand how processes and activities are organized and optimized to obtain reliable, safe and compliant results with the standards in force.

Basic concepts of quality management are part of the area of disciplines oriented towards the development of the necessary skills for understanding, applying and evaluating quality processes within medical institutions. This course unit introduces trainees to the fundamental principles of quality management, specific terminology and the importance of the systemic approach in ensuring safe, efficient and beneficiary-oriented services. It is a fundamental course unit for the training of quality technicians who will work in medical institutions. In the current context, health systems are in a continuous process of transformation, where the requirements regarding patient safety, compliance with standards, process traceability and professional responsibility are increasingly high. In this complex environment, the role of the quality technician becomes essential for ensuring and improving the quality of medical services.

The course provides the necessary basis for understanding the principles and terminology of quality management, essential for interpreting how clinical and administrative processes are organized, monitored and optimized. By studying these concepts, trainees develop the ability to analyze workflows in medical institutions, identify risks, non-conformities and opportunities for improvement.

The course unit contributes to the development of the necessary skills for the technician in the medical field to:

- correctly interpret documents and procedures specific to quality management;
- participate in monitoring activities;
- to support the implementation and maintenance of quality management systems in medical institutions;
- participate in the collection and analysis of quality data;
- identify non-conformities and risks;
- to document processes correctly;
- to support the implementation of continuous quality improvement actions in the medical institution;
- to understand the role of quality in ensuring patient safety and increasing the efficiency of the medical institution.

During the course, future quality technicians will be guided to understand the structure of a health quality management system, the responsibilities of each actor involved, and how

evaluation tools (audits, observation sheets, performance indicators) contribute to increasing institutional efficiency.

Through this context, the course unit serves as a basis for subsequent course units, contributing to the development of a responsible professional attitude, oriented towards compliance with quality requirements, error prevention, understanding the importance of processes and an evidence-based approach and indicators. Through this, the course contributes to the formation of an organizational culture focused on quality and continuous improvement of the medical services provided.

II. MOTIVATION, USEFULNESS OF THE COURSE UNIT FOR PROFESSIONAL TRAINING

The course unit *Basic Concepts of Quality Management* is essential for the training of the quality technician in the medical field, as he/she works in an environment where patient safety, process efficiency and compliance with standards are fundamental priorities. In medical institutions, the quality of services depends on how clinical and administrative processes are organized, monitored and improved, and the quality technician has a direct role in supporting these activities.

The motivation for studying this course unit stems from the need to align medical institutions with international standards, such as ISO 9001 and healthcare accreditation requirements, which require trained personnel capable of actively participating in the implementation and maintenance of quality management systems. In addition, the formation of a quality-oriented organizational culture involves personnel aware of their role in complying with procedures, in correctly documenting activities, in constantly monitoring processes and in actively contributing to the continuous improvement of services.

Therefore, this course unit plays a decisive role in preparing quality technicians for competent integration into medical teams, contributing to ensuring a safe, efficient and quality-compliant environment, in which clinical and administrative processes are continuously monitored, evaluated and improved.

The usefulness of the course unit consists in developing the practical and theoretical skills necessary for the technician to:

- Monitoring and evaluating clinical and administrative processes in medical institutions to ensure compliance with quality standards;
- Use of quality control tools: internal audits, observation sheets, performance indicators.
- Identifying non-conformities and risks that may affect patient safety and the efficiency of activities.
- Contribution to the implementation of measures for the continuous improvement of medical services, through recommendations and participation in process optimization projects;
- Efficient integration into the medical team and compliance with national and international quality standards, promoting an organizational culture oriented towards safety and excellence.

III. PROFESSIONAL COMPETENCES SPECIFIC TO THE COURSE UNIT

At the end of the course unit, the trainee will be able to:

SC1. Apply the fundamental concepts of quality management in medical institutions.

SC2. Monitor and evaluate clinical and administrative processes for the safety and quality of services .

SC3. Contribute to the continuous improvement of procedures and processes through the use of quality control tools.

IV. COURSE UNIT ADMINISTRATION

Unit status course	Number of hours					Assessment form	No. of credits
	Total hours	Direct contact	Individual study/ Practical activities	Direct contact			
				notional	Practicals/Seminars		
compulsory	**150**	**50**	**100**	**30**	**20**	**T/P**	**5**

V. CONTENT/LEARNING UNITS

Unit competences	Content/learning units	Study goals/skills
Learning Unit 1. The Health System		
UC 1.1 Identifying the structure, functioning and governance of the health system in different countries, by analyzing the levels of organization (primary, secondary, tertiary), evaluating the management and functioning of health services	1.1. The healthcare system in Moldova/France/Greece/Romania 1.1.1. Characteristics of the health system. 1.1.2. Organization of the health system (primary, secondary, tertiary healthcare), the duties of each actor in the system. 1.1.3. Financing the health system.	▪ Describe the structure of the health system in different countries, identifying the levels of organization: primary, secondary and tertiary. ▪ Explain how health services operate and are managed, including coordination, financing, and governance mechanisms. ▪ Identify the main actors of the health system and explains their roles and responsibilities in providing services. ▪ Comparatively analyze different health systems, highlighting similarities, differences and the impact of organization on the performance of medical services.
UC 1.2 Analyzing the structure, processes, financing mechanisms, councils/committees and functional circuits of the healthcare organization (hospital).	1.2. Organization and operation of the health unit with beds - hospital. 1.2.1. Structure 1.2.2. Process 1.2.3. Financing 1.2.4. Councils and committees 1.2.5. Functional circuits in the hospital	▪ Identify the structure and main processes in a hospital, including wards and workflows. ▪ Explain the financing method and the role of councils/committees in organizing and coordinating hospital activities. ▪ Analyze functional circuits (patients, staff, medications, materials) and their impact on the quality and safety of medical services.
Learning unit 2. Quality, standardization . Accreditation procedure.		

Unit competences	Content/learning units	Study goals/skills
UC 2.1. Recognizing and understanding the definitions of quality, the evolution of the concept of quality, the principles of total quality and the characteristics of care services, to substantiate the application of quality management in the health field. **UC 2.2** Understanding the role and evolution of standardization systems. **UC 2.3** Knowledge and application of the concepts of accreditation and quality certification in medical institutions.	2.1. Quality 2.1.1 Definitions, evolution of the concept of quality, total quality 2.1.2. Quality management concepts (quality assessment, quality assurance, quality improvement, PDCA/PDSA cycle) 2.1.3. Quality Management System (QMS) 2.1.4. SMQ principles, characteristics of care services 2.2. Standardization 2.2.1. The role and importance of standardization 2.2.2. Evolution of standardization systems 2.3. Accreditation 2.3.1. What is accreditation? 2.3.2. The importance of accreditation and the stages of the accreditation process 2.3.3. Accreditation/certification 2.3.4. Other quality certification methods (ISO certifications, certification of medical analysis laboratories, radiological opinion)	▪ Describe the definitions of quality and explain the evolution of the concept in the healthcare field. ▪ Identify and explain the principles of total quality and their applicability in care services. ▪ Analyze the characteristics of medical services to substantiate the application of quality management in professional practice. ▪ Describes the role of standardization in ensuring the quality of services and processes. ▪ Explain the evolution of standardization systems at national and international level. ▪ Analyze the applicability of standards in medical institutions to improve quality and patient safety. ▪ Describes the role and importance of accreditation in ensuring the quality of medical services. ▪ Explain the steps of the accreditation process and the differences between accreditation and certification. ▪ Analyze the main methods of quality certification, including ISO standards, medical laboratory accreditation, and radiological approvals.
Learning unit 3. Processes, documents, indicators, flows.		
UC 3.1 Management of quality processes and documents in medical institutions.	3.1. Processes - types of processes 3.2. Quality documents (procedures, guides, protocols) 3.3. Indicators (introduction, development, control) 3.4. Flow - development of process flows, flow and process analysis 3.5. Practical applications – preparation of quality documents	▪ Identify and correctly define processes in medical institutions. ▪ Propose and use evaluation indicators to monitor process performance. ▪ Create and manage quality documents, ensuring compliance with standards and continuous improvement of medical services.

VI. INDICATIVE DISTRIBUTION OF HOURS BY CONTENT/LEARNING UNITS

No. crt.	Content/learning units	Number of hours				
		Total	Direct contact	Individual study/Practical activities	Direct contact	
					notional	Practicals/seminars
1.	The health system.	**30**	**10**	**20**	**6**	**4**
2.	Quality, standardization. Accreditation procedure.	**90**	**30**	**60**	**18**	**12**
3.	Processes, documents, indicators, flows.	**30**	**10**	**20**	**6**	**4**
Total		**150**	**50**	**100**	**30**	**20**

VII. TEACHING-LEARNING SUGGESTIONS

To ensure a thorough understanding of the fundamental concepts of quality management and to develop the practical skills of trainees, it is recommended to use a variety of teaching-learning methods and techniques, integrating theory with practical activities and case studies.

1. Theoretical teaching

- Lecture: presentation of quality definitions, total quality principles, quality management concepts and quality management systems.
- Presentation: illustrating the application of quality principles in medical institutions, including by presenting quality processes and documents.
- Use of visual materials: schemes, diagrams, process flow charts and graphs that highlight quality monitoring and improvement mechanisms.

2. *Practical exercises*

- Case study analysis: examining real examples of quality management implementation in healthcare institutions, identifying good practices, problems and solutions.
- Exercise: trainees define processes, propose performance indicators, and develop operational flows.
- Quality assessment simulation: applying the concepts of quality assurance, assessment and improvement to hypothetical situations.

3. *Participatory methods*

- Guided discussions and brainstorming: trainees identify real problems related to quality management and propose solutions.
- Teamwork: developing action plans to improve the quality of processes in medical institutions.
- Presentations and feedback: trainees present the conclusions of practical activities, receive feedback and discuss ways to apply them in practice.

4. *Teaching resources*

- Manuals and guides on quality management and international standards (ISO, ISO 9001, etc.).

- Internal documents of medical institutions regarding processes, flows and quality indicators.
- Online resources: articles, educational platforms and interactive case studies.

VIII. ASSESSMENT SUGGESTIONS

The assessment of trainees is carried out through a combination of theoretical and practical methods, to verify both knowledge of fundamental concepts and the ability to apply them in real contexts in medical institutions.

Formative assessment aims to monitor the progress of trainees during the learning activities, providing continuous feedback and support for the consolidation of knowledge and the development of practical skills in quality management.

Main features :

- It is continuous, carried out throughout teaching-learning activities.
- It focuses on the process, not just the final product.
- It allows for quick correction of mistakes and improvement of trainees' performance.

Current / formative assessment methods:

- Questions and answers during lectures – checking understanding of theoretical concepts.
- Group discussions – assessment of analysis and argumentation capacity.
- process identification , flow development and proposal of performance indicators.
- Case study analysis – assessing critical thinking, the ability to identify problems and propose solutions.
- Individual or group feedback – provided immediately after activities, to correct and consolidate knowledge and skills.

Summative assessment aims to verify the final level of knowledge, skills and competences acquired by trainees at the end of the course unit, ensuring that they can apply the concepts and tools of quality management in medical institutions. Summative assessment aims at the final assessment of acquired skills, combining theoretical verification, practical application, and communication and analysis skills.

evaluation methods are:

- ***The test*** **,** which includes:
  - ✓ Objective grid-type questions to verify understanding and memorization of fundamental concepts.
  - ✓ Open-ended questions, which require explanation and argumentation of quality concepts, total quality principles, QMS and the role of accreditation and certification.
  - ✓ Application problems, through which trainees must interpret hypothetical situations in a medical institution or medical laboratory and propose solutions according to quality standards.

The assessment test aims to verify the understanding of fundamental quality management concepts, assess the ability to analyze and interpret theoretical information in practical contexts.

evaluation criteria for the assessment test focus on: the correctness of the answers, the clarity and structure of the presentation of ideas, the ability to apply theoretical concepts in practice.

- ***Applied project,*** which involves:

- ✓ Defining and classifying processes in a medical institution.
- ✓ Building operational flows and identifying critical points.
- ✓ Proposing and calculating performance indicators for quality monitoring.

Evaluation criteria of the application project are based on: the correctness and applicability of flows and indicators, the structure and clarity of quality documents, compliance with quality principles, originality and ability to critically analyze the proposed situation.

- ***Individual or group presentation*** is an assessment method that aims to measure both the theoretical knowledge of trainees and their ability to apply quality management concepts in practical contexts. Through this method, trainees present their analysis of a case study, application project or practical exercise carried out during the course unit. The presentation involves explaining the developed process flows, describing the proposed performance indicators and the quality documents produced, as well as arguing the proposed solutions and recommendations. This summative assessment method aims to develop communication and professional presentation skills, demonstrate the ability to synthesize, analyze and apply QMS concepts, and argue the proposed solutions in accordance with quality standards and principles.

  Advantages of summative assessment are:

- ✓ It ensures a complete assessment of the trainees' knowledge and skills, combining theoretical verification and practical application.
- ✓ It allows the assessment of critical thinking, analytical skills and the application of QMS tools in real or simulated contexts.
- ✓ It provides an objective basis for the final grade, reflecting both knowledge and practical skills and professional communication skills.

This combination of formative and summative assessment allows trainees to integrate theory with practice, correctly identify processes and flows, develop quality indicators and documents, and apply QMS in medical institutions.

IX. SUGGESTIONS FOR INDIVIDUAL STUDY

Subjects for individual study	Products to be developed	Assessment methods	Completion time, hours
Definitions of quality, principles of total quality, evolution of the concept of quality.	Summary/study sheet, comparative diagrams between concepts.	Summary feedback	12
The concept of quality management (quality assessment, quality assurance, quality improvement, PDCA/PDSA cycle).	Practical application sheet with examples of PDCA/PDSA application in a medical institution.	Assessment of the application form	14
The quality management system (QMS) and its principles.	Diagram of a QMS applied in a medical institution, with flows and processes.	Chart assessment	14
Accreditation and quality certification.	Short comparative report between accreditation, ISO certification and other certification methods .	Content analysis assessment	14
25Identification and	Developing a process flow	Assessment of	14

Subjects for individual study	Products to be developed	Assessment methods	Completion time, hours
development of processes, performance indicators.	and proposing 3 performance indicators.	process performance indicators	
Quality documents (procedures, instructions, forms).	Writing a procedure or instruction.	Document assessment	20
Analysis of case studies on quality management.	Case study analysis sheet identifying problems and proposing solutions.	Assessment of the analysis sheet	12
Total			**100**

X. SUGGESTIONS FOR PRACTICAL ACTIVITIES

Practical activities are an essential component of the learning process within the course unit *Basic Concepts of Quality Management* , as they allow trainees to apply theoretical concepts in real or simulated contexts in medical institutions. By carrying out these activities, trainees develop fundamental practical skills, such as identifying and classifying processes, building operational flows, proposing and monitoring performance indicators, drafting quality documents and analyzing complex situations that affect the quality of medical services. These activities aim to stimulate critical thinking, the ability to analyze and synthesize, communication skills, teamwork and professional responsibility of trainees.

One of the main recommended practical activities is ***the analysis of case studies.*** In this activity , trainees examine real case studies, taken from medical institutions, or hypothetical ones, that reflect quality problems, incidents or deficiencies in medical processes. The analysis involves identifying major problems, assessing their impact on patients and the services provided, as well as proposing solutions and improvement measures. The objectives of this activity are to develop critical and analytical thinking, apply the principles and concepts of the quality management system to evaluate the efficiency and quality of medical services and formulate concrete recommendations for improving patient quality and safety. The activity can be carried out individually or in small groups, and trainees complete an analysis sheet that includes a description of the situation, identification of problems, analysis of causes and proposal of solutions. Finally, guided discussion sessions are organized with the trainer, during which the proposed solutions are argued and the approaches of the different groups are compared.

A second recommended practical activity is ***the process definition and development exercise*** . In this activity, trainees identify the main and secondary processes in a medical institution, classify them and develop operational flows that reflect the correct sequence of activities and the responsibilities of each stage. In addition, trainees propose performance indicators corresponding to each process, so that their efficiency and quality can be monitored objectively. The objectives of the activity are to acquire the ability to identify and classify processes in a medical institution, to develop planning and graphical representation skills of process flows, highlighting critical points and areas with risk of errors, as well as to understand how to monitor and evaluate process performance through appropriate indicators. The activity can be carried out individually or in small groups. Trainees develop graphical process flows, with clearly defined stages and assigned responsibilities, as well as

sheets with performance indicators for each process, justifying their choice. Evaluation is carried out by checking the flows for clarity, correctness and applicability, assessing the relevance, feasibility and measurability of the proposed indicators and providing detailed feedback from the trainer and peers.

A third practical activity is ***quality assessment simulation*** . In this activity, trainees participate in simulated quality assessment exercises, in which they apply the concepts of quality assurance, assessment and improvement. Examples of activities include: simulating an internal audit, analyzing hypothetical incidents, identifying non-conformities and proposing corrective measures. The objectives of this activity are to understand how to evaluate the quality of medical services through specific QMS tools, develop the ability to make correct decisions in simulated situations, applying the principles of total quality, and increase the skills of planning improvement measures and monitoring results. The activity is usually carried out in small groups, with pre-established roles, such as auditor, process manager or coordinator, and trainees analyze hypothetical situations, identify deficiencies and propose corrective solutions. A detailed report is written that includes the conclusions of the analysis and recommended measures. The assessment is carried out by analyzing the written report, for structure, clarity, relevance and correctness of the proposed solutions, by observing the trainees' involvement in the simulation and the ability to apply theoretical knowledge, as well as by providing individual and group feedback on the proposed approach and solutions.

A fourth practical activity is ***the development of quality documents*** . In this activity, trainees draft essential documents for quality management, such as procedures, work instructions, monitoring forms or guides for specific processes. The documents must be clear, coherent, applicable and comply with the norms and standards of the quality management system . The objectives of the activity are to develop skills in documenting and structuring information, correctly applying the principles of QMS in drafting documents and ensuring the clarity, coherence and applicability of documents created for medical staff. The activity can be carried out individually or in groups, based on a previously identified process. Trainees draft the documents and check them through internal feedback, then submit them for review to the trainer. The evaluation is carried out by checking the correctness and applicability of the documents, compliance with the standard format and QMS terminology, as well as the clarity of the information and the ability to use the documents in practice.

A fifth and final recommended activity is ***the implementation of integrated activities*** , which combine the analysis of case studies, the definition of processes, the development of operational flows, the proposal of indicators and the drafting of quality documents. This activity allows trainees to consolidate theoretical and practical knowledge in a coherent and applicable project. The objectives of the activity are to consolidate theoretical and practical knowledge in quality management, to develop planning, analysis, synthesis and documentation skills, as well as to prepare trainees for the application of QMS in real work in medical institutions. The activity can be carried out individually or in groups, based on a real or simulated process or situation. Trainees develop the flows, indicators, documents and situation analysis, then present the complete project to the trainer and colleagues. The assessment is carried out by checking the project presentation for coherence, applicability and correctness, evaluating documents, flows and performance indicators, as well as by

assessing the trainees' ability to argue and justify the proposed solutions and their active involvement in discussions and feedback.

This set of suggestions for practical activities ensures active, applied and integrated learning , which develops both theoretical and practical skills essential for the application of quality management in healthcare institutions, providing trainees with the necessary tools to identify and resolve quality issues, develop documents and implement continuous improvement measures.

XI. TEACHING RESOURCES RECOMMENDED FOR TRAINEES

1. Armean, Petru . *Quality management of health services,* Bucharest Publishing House, 2002
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3. Furtunescu , Florentina-Ligia, Mincă, Dana- Galieta . *Health services management – project approach,* 2nd revised and completed edition , *Carol Davila* University Publishing House, Bucharest , 2010