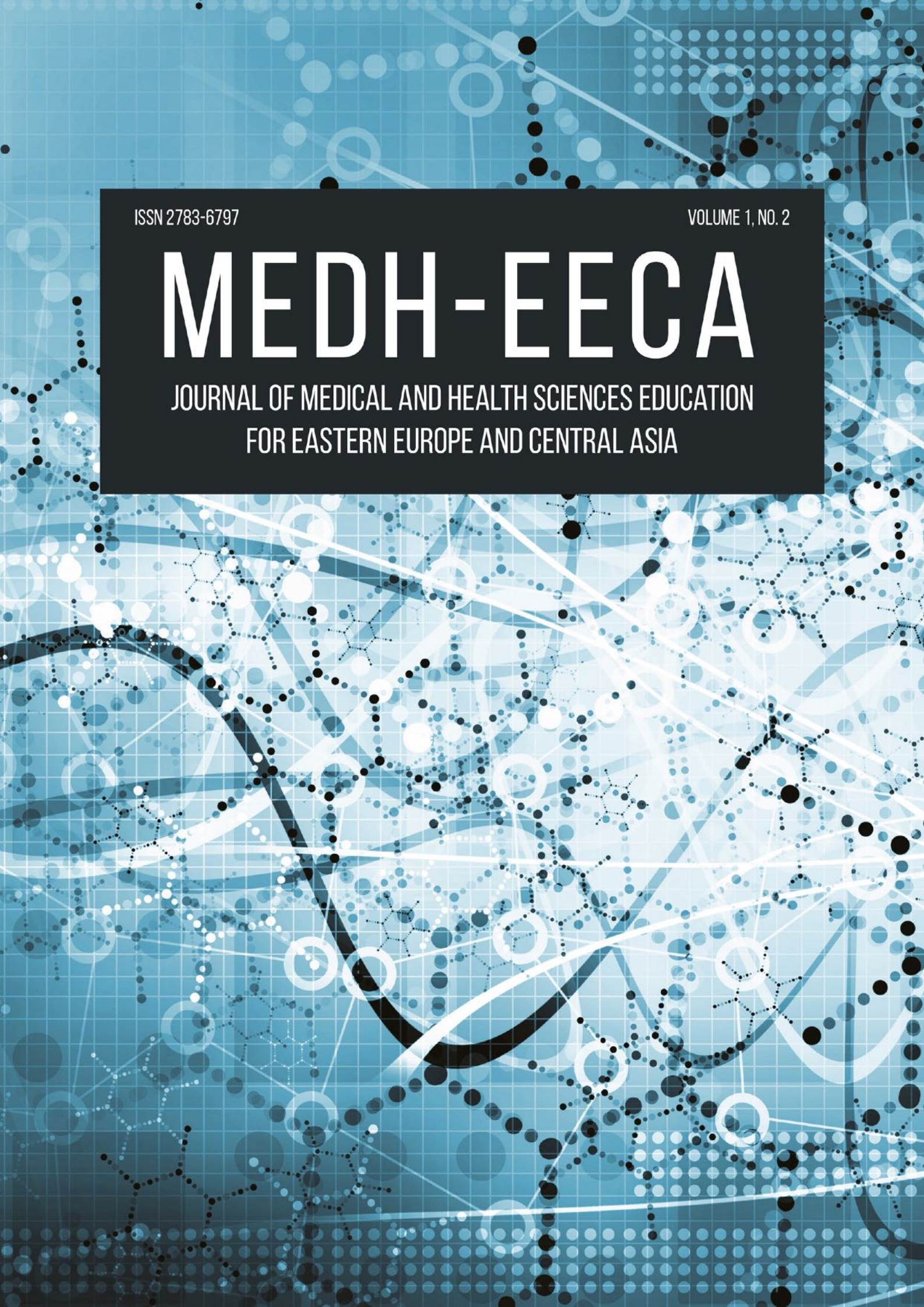
ISSN 2783-6797

VOLUME 1, NO. 2

MEDH-EECA

JOURNAL OF MEDICAL AND HEALTH SCIENCES EDUCATION FOR EASTERN EUROPE AND CENTRAL ASIA



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Aims and Scope
The Journal of Medical and Health Sciences Education for Eastern Europe and Central Asia (MEDH-EECA, ISSN 2783-6797 is an annual, peer-reviewed, international general research and practice journal).
The purpose of the MED-EECA is to advance knowledge and disseminate research findings that are directly relevant to the practice of health science education, including multiple fields of medical, public health, nursing, and pharmaceutical training. The journal publishes scholarly papers on all aspects of health science education including: peer review evaluation and case studies; institutional accreditation and training programme accreditation related materials; the theory, practice and policies relating to management, improvement of quality in medical and other health sciences education; new initiatives and models in learning and teaching that impact on quality and standards; links between quality assurance and employability of healthcare staff; evaluation of the impact of quality procedures at national level; theoretical and practical analyses of quality and quality initiatives in health science training; comparative studies between institutions or countries, etc.
In particular, the journal specifically aims to become a platform available for Eastern European and Central Asian countries to share the new ideas and demonstrate rapid and significant advancements in reforming the training of human resourses for healthcare.
Original articles with scientific investigations and systematic literature reviews are welcomed from professionals of other health related fields on issues that have a direct impact on the area of staff training and strengthen evidence-based practice. Letters to the editor with commentaries on published papers or research and clinical issues, as well as short communications, will be taken into consideration and not left unanswered. This journal also provides space for announcements and an international calendar for professional conferences in the area of training of healthcare professionals.

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Co-funded by the
Erasmus+ Programme
of the European Union

ERASMUS+ PROJECT SPRING

SETTING PEER REVIEW INSTRUMENTS AND GOALS FOR MEDICAL (HEALTH) EDUCATION

Multinational Peer Review Board (MPRB)
QUALITY ASSURANCE STANDARDS FOR PEER REVIEW IN HIGHER EDUCATION INSTITUTIONS
Self-Evaluation Report-version

These standards were developed by the participants of the SPRING project
609528-EPP-1-2019-1-GE-EPPKA2-CBHE-JP (2019-1937/001-001)
and were approved by MPRB on Feb. 8, 2021

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STANDARD 1. Vision, mission and strategic objectives

Description: The Higher Education Institution (HEI) presents the published vision and mission statements that reflect its commitment to continuous quality enhancement; The HEI describes the strategic objectives and clear policies and procedures that are consistent with its vision and mission.

CHECKLIST
1.1. The vision and mission and strategic objectives and HEI and commitment to quality enhancement.
1.2. How the forms of planning (for example, strategic, institutional, academic, and financial) are coordinated to ensure the quality of academic outcomes.
1.3. How medium- and long-term plans of HEI reflect the programmes being offered, as well as its research focus to ensure sustainability and continuous improvement.
1.4. Formulation and approval of the plans (collegiality, do they promote a high degree of institutional integrity and responsiveness to change, are known to stakeholders).
1.5. How continuous and periodic monitoring, evaluation, and benchmarking of processes, including self-assessment of academic programmes and institutional self-assessment for purposes of continual improvement is provided.

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STANDARD 2. Governance and management

Description: The institution shall have clearly stated governance and management structures. This will ensure sound and ethical governance and management, including robust QA practices that support the achievement of its mission and legal mandate.

CHECKLIST
2.1. How HEI develops qualified, competent, and experienced leadership to oversee the development and management of a quality culture within the institution.
2.2. How relevant governance and management bodies, such as the University Council, Senate, Management Board, Student Body; and various committees, each with a clear mandate, duties, responsibilities, powers, privileges, and tenure; and these bodies are coordinated to ensure efficiency, effectiveness and quality.
2.3. How HEI warranty the QA policy and structure, which flow down through all levels.
2.4. Description of how clear communication systems and networks for the promotion of internal and external information dissemination for public accountability are.
2.5. Has or not policies and procedures for the delegation of authority, whenever needed.
2.6. How HEI enables students to participate in decision-making in relevant governance bodies.
2.7. How HEI ensures regular consultations with stakeholders, reports and follows up actions on key issues of policy and operations to promote quality, cohesion, harmony, and identity within the institution.
2.8. How HEI emphasises ethics, transparency, and academic integrity throughout its teaching, learning and research activities.

2.9. Description how HEI publishes and disseminates on a regular basis, impartial and objective qualitative and quantitative information about courses offered, research undertaken and community services.
2.10. How HEI developed and implemented effective processes for deterring, detecting, and dealing with misconduct by students or staff;
2.11. Description of how effective, systematic, timely and fair processes for the investigation of complaints is, grievances and appeals by students, staff, and other stakeholders.

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STANDARD 3. Human resources

Description: The institution shall have policies on human resources that are inclusive, and that ensure recruitment and retention of adequate numbers of qualified and competent staff to achieve its mission and carry out its legal mandate.

CHECKLIST
3.1. How HEI implement clear policies and procedures that ensure equal opportunities and equality in human resources for recruitment, retention, and promotion of staff that is based on qualification, competence, and skills.
3.2. How HEI keeps a core of full-time staff up-to-date records, information of staff numbers, qualifications, and employment turnover rates.
3.3. Description of policies and procedures for continuous staff development.
3.4. Description focusing on how clear the contractual agreements with staff are which outline the conditions of employment and are aligned with any legislative requirements of the country of the institution.
3.5. How HEI provides adequate staff support facilities and services.
3.6. How HEI undertakes periodic monitoring, evaluation, and appraisal of staff.

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STANDARD 4. Financial resources management

Description: The institution shall have adequate financial resources and prudent financial management that are aligned to its mission, objectives, and mandate to ensure quality education.

CHECKLIST
4.1. Description of how HEI provides adequate financial resources to carry out its mandate and objectives effectively and efficiently
4.2. How HEI assures the diversified financial and sustainable resource base and ensures a balanced allocation of resources to core functions of teaching and learning, research, and community engagement.
4.3. Presenting how HEI ensures a prudent financial management system, which includes strategies, policies and procedures for budgeting, resource allocation, repairs and maintenance of infrastructure, asset management, debt management and financial reporting.

4.4. How monitoring, evaluation (through financial audits) and benchmarking processes for the financial management system using international best practices or some other basis of accounting appropriate for the institution is provided.

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STANDARD 5. Infrastracture and facilities

Description: The institution shall have adequate and appropriate infrastructure, facilities, and resources to support teaching, learning and research.

CHECKLIST
5.1. Description of academic, administrative, and recreational facilities (lecture theatres, seminar rooms, staff offices, laboratories, studios, workshops, etc.) adequate for the number of students and staff.
5.2. Description how properly university library is organised and equipped with facilities and resources (physical and/or electronic), adequate for the number of students and staff.
5.3. Description on adequate Information and Communication Technology (ICT) infrastructure, including affordable, high speed and dedicated connectivity.
5.4. Description of facilities that conform to appropriate national health and personnel safety provisions.
5.5. Description of facilities accessible for persons with disabilities.

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STANDARD 6. Student recruitment, admission, certification and support services

Description: The institution shall have pre-defined, published, and consistently applied policies and procedures that ensure fair and equitable recruitment and admission, progression, certification and support services through all phases of the student's lifecycle, and in issues concerning students' future employability.

CHECKLIST
6.1. Description procedures for marketing/promoting the institution and its programmes, recruitment, admission, selection and registration
6.2. How procedures that promote diversity in admission, including gender mainstreaming and consideration of disadvantaged groups and persons with disabilities, where applicable are provided.
6.3. Description of how university ensures that students admitted meet minimum general and programme specific entry requirements.
6.4. Description of how the university ensures monitoring, evaluation, and benchmarking for improvement of enrolment management.
6.5. Description of how the university promotes the student retention and progression, and address issues concerning drop-out rates.
6.6. Description of how the university ensures the storage of detailed records and transcripts, indicating the list of courses, units and grades.

6.7. Description of how the university promotes adequate provision for information and advice to potential students during the application and enrolment phases.

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STANDARD 7. Educational programme

7A. Educational programme objectives, learning outcomes and their compliance with the programme

Description: A programme has clearly established objectives and learning outcomes, which are logically connected to each other. Programme objectives are consistent with the mission, objectives, and strategic plan of the institution. Programme learning outcomes are assessed on a regular basis in order to improve the programme.

CHECKLIST
7.1.1. Programme objectives define the set of knowledge, skills, and competences the programme aims to develop in graduate students. They also illustrate the contribution to the development of the field and the society.
7.1.2. Programme encompasses the health needs of the community, the needs of the healthcare delivery system and other aspects of social accountability and the same time aspects of global health.
7.1.3. Programme aim and educational strategy result in a graduate medical doctor competent at a basic level, and at the same time has an appropriate foundation for future career in any branch of medicine.
7.1.4. Programme learning outcomes assessment cycle consists of defining, collecting, and analysing data.
7.1.5. Programme learning outcomes assessment results are utilised for the improvement of the programme.

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7B. Programme structure, teaching methodology and organisation, adequate evaluation of programme mastering

Description: Programme structure, design, content, teaching and learning methods and student assessment ensure the achievement of programme objectives and intended learning outcomes.

CHECKLIST
7.2.1. Programme is designed according to HEI's methodology for planning, designing, and developing of educational programmes.
7.2.2. Programme structure is consistent and logical.
7.2.3. Programme content and structure ensure the achievement of programme learning outcomes.
7.2.4. Qualification to be granted is consistent with the programme content and learning outcomes.
7.2.5. Student learning outcomes of each compulsory learning course/module are in line with programme learning outcomes; moreover, each course/module content and number of credits correspond to course learning outcomes.

7.2.6. Teaching materials listed in syllabi are based on the core and modern achievements in the medical field and ensure the achievement of intended programme learning outcomes.
7.2.7. Programme content, extent and sequencing of courses and other curricular elements ensure appropriate coordination between basic biomedical, behavioural, and social and clinical subjects.
7.2.8. Programme ensures the development of students' clinical knowledge and skills.
7.2.9. Programme identifies and incorporates the contributions of the clinical sciences.
7.2.10. Programme provides updated knowledge in the clinical sciences in scientific, technological, and clinical developments, current and anticipated needs of the society and the healthcare system.
7.2.11. Programme ensures that every student has early patient contact gradually, including participation in patient care.
7.2.12. Programme structure ensures that, structure the different components of clinical skills training according to the stage of the study programme.
7.2.13. Programme contains modern and updated contributions of the behavioural and social sciences as well as a new approaches in medical ethics and medical jurisprudence too.
7.2.14. Programme ensures the development of students' practical, scientific/research/creative/performance and transferable skills and/or their involvement in research projects, in accordance with the programme learning outcomes.
7.2.15. Programme provides graduate with scientific knowledge, concepts, and methods fundamental to acquiring and applying clinical science.
7.2.16. Programme provides graduate with knowledge and competences in medical research methods and evidence-based medicine and analytical, critical thinking and clinical reasoning skills.

This sub-standard should be filled in case of an integrated programme
7.2.17. The degree of integration corresponds to the Harde's scale – level (these should be written in the comment column level of integration).
7.2.18. Programme ensures horizontal integration of associated sciences, disciplines, and subjects.
7.2.19. Programme ensures vertical integration of the clinical sciences with the basic biomedical and the behavioural and social sciences.
7.2.20. Programme allows optional (elective) content and defines the balance between the core and optional content as part of the educational programme.
7.2.21. Programme is implemented using student centred teaching and learning (SCL) methods. Teaching and learning methods correspond to the level of education, course content, student learning outcomes and ensure their achievement.
7.2.22. Student evaluation is conducted in accordance with the established procedures.
7.2.23. It is transparent and complies with existing legislation.
7.2.24. Assessment methods are varied and modern.
7.2.25. Assessment principles, methods and practices provide an appropriate balance of formative and summative assessment to guide both learning and decisions about academic progress.

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7C. Student achievements and individual work with them

Description: HEI creates student-centred environment by providing students with relevant services; programme staff ensures students' familiarity with the named services, organises various events and fosters students' involvement in local and/or international projects.

CHECKLIST
7.3.1. Students receive appropriate consultations and support regarding the planning of learning process, improvement of academic achievement, employment, and professional development.
7.3.2. Students have qualified supervisors, or mentors, or tutors who guide them for academic or/and social needs.

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7D. Providing teaching resources

Description: Programme human, material, information, and financial resources ensure programme sustainability, its effective and efficient functioning, and achievement of intended objectives.

CHECKLIST
7.4.1. Programme staff consists of qualified people who have necessary competences in order to help students achieve programme learning outcomes.
7.4.2. The number and workload of programme academic/scientific and invited staff ensures the sustainable running of the educational process and also, proper execution of their research/creative/performance activities and other assigned duties. Balance between academic and invited staff ensures programme sustainability.
7.4.3. The Head of the Programme possesses necessary knowledge and experience required for programme elaboration. He/she is personally involved in programme implementation.
7.4.4. Programme students are provided with an adequate number of administrative and support staff of appropriate competence.
7.4.5. HEI conducts the evaluation of programme academic, scientific, and invited staff and analysis evaluation results on a regular basis.
7.4.6. HEI fosters professional development of the academic, scientific, and invited staff. Moreover, it fosters their scientific and research work.
7.4.7. Programme is provided by necessary educational resources and technical equipment required for achieving programme learning outcomes.
7.4.8. The allocation of financial resources stipulated in programme/faculty/school budget is economically feasible and corresponds to programme needs.
7.4.9. Programme is administrated in a way which allows successful implementation.

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7E. Teaching Quality Enhancement Opportunities

Description: In order to enhance teaching quality, programme utilises internal and external quality assurance services and also periodically conducts programme monitoring and programme review. Relevant data is collected, analysed, and utilised for informed decision making and programme development on a regular basis.

CHECKLIST
7.5.1. Programme staff collaborates with internal quality assurance service(s) available at the higher education institution when planning the process of programme quality assurance, creating assessment instruments, and analysing assessment results. Programme staff utilises quality assurance results for programme improvement.
7.5.2. Programme utilises the results of external quality assurance on a regular basis.
7.5.3. Programme monitoring and periodic review is conducted with the involvement of academic, scientific, invited, administrative staff, students, graduates, employers, and other stakeholders through systematically collecting and analysing information. Assessment results are utilised for programme improvement.
7.5.4. HEI has a curriculum committee, which under the governance of the academic leadership (the dean) has the responsibility and authority and is planning and implemented innovations in the curriculum.

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STANDARD 8. Research and innovation

Description: The institution shall encourage, promote, engage in innovative research consistent with its policies and strategic plans, and address national, regional, continental and international needs. The institution shall encourage innovation in its teaching, learning and research. The institution shall ensure that the management of postgraduate studies are conducted within an approved framework of institutional policies and plans that ensure quality ethical research.

CHECKLIST
8.1. There is a shared understanding of the nature, role and goals of research.
8.2. There are standards, procedures, and processes for the approval of research proposals, and theses, and the conduct and supervision of research studies.
8.3. There are policies, research management systems and strategies, adequate infrastructure and resources that facilitate all staff to undertake innovative research and publish research results.
8.4. The research undertaken is relevant and responsive to the needs for academic advancement and community development expectations.
8.5. There is effective monitoring and evaluation of the research system.

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STANDARD 9. Community engagement

Description: The institution shall encourage engagement in community outreach programmes as part of its social responsibility.

CHECKLIST
9.1. The institution ensures that community engagement activities are conducted within institutional policies and strategies that facilitate collaboration between the institution and its larger communities (local, national, regional, continental, and global) for the mutually beneficial exchange of knowledge and resources in a context of partnership and reciprocity.
9.2. Institution incorporates community engagement in its activities, with the objective of: a) Enriching scholarship, research, and creative activities; b) Enhancing teaching and learning; c) Facilitating preparation of educated and engaged citizens; d) Strengthening the democratic values and civic responsibility in students; e) Addressing critical societal issues and contributing to public good.

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STANDARD 10. Information management system

Description: The institution shall ensure that it collects, analyses, and makes use of relevant information for the effective management of its programmes of study and other activities.

CHECKLIST
10.1. Key performance indicators.
10.2. Profile of student population.
10.3. Learning resources and available student services.
10.4. Student progression, drop-out rates, and graduation rates.
10.5. Satisfaction of students and alumni with programmes and teaching provided.
10.6. Career paths for students.

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STANDARD 11. Public communication

Description: The institution shall publish information about its activities, including programmes, in a clear, accurate and objective manner; and ensure that the information is up-to-date and accessible. The institution shall ensure that promotion of its programmes is carried out in a fair and ethical manner, following acceptable best practices, and complies with all relevant legislation.

CHECKLIST
11.1. Promotional materials give a clear and accurate view of the programme, its provision, objectives, and outcomes, including: A. Identification of the programme, B. The body awarding the qualification and its accreditation status; C. Mode of delivery, D. Level of the programme on the National Qualifications Framework (NQF), where applicable, E. Charges involved, F. Terms and conditions relevant to the programme, G. Conditions for withdrawal from the programme, H. Financial agreements with the provider; and I. Rights, obligations and commitments expected of the student.
11.2. Students are fully informed of the issues that affect them with respect to the management of the programme, such as: A. Language of communication B. Timeframe in which the programmes are

offered and nature of learning outcomes, C. Required texts and access to reference materials, D. Understanding of independent learning expectations E. Schedule for examinations, F. Schedule for submission of assignments, and G. Collection of certificates.

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STANDARD 12. Collaboration, staff and student mobility

Description: The institution shall have mechanisms that promote collaboration with other HEIs, professional bodies, research institutions and relevant social actors at national, regional, continental, and international levels and to facilitate mobility of students and staff.

CHECKLIST
12.1. The institution has policies that promote the mobility of academic staff, researchers, and students in the programme, internationally.
12.2. Ensure that students benefit from the same standard of resources as those for the regular students of the awarding institution.
12.3. Ensure that the collaborating institutions are approved by the relevant QAA/ professional body and are subject to periodic quality audits.
12.4. Ensure that students are fully informed of the nature of the collaboration between the institutions concerned.

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Co-funded by the
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SETTING PEER REVIEW INSTRUMENTS AND GOALS FOR MEDICAL (HEALTH) EDUCATION

SETTING PEER REVIEW INSTRUMENTS AND GOALS IN MEDICAL (HEALTH) EDUCATION SPRING

Multinational Peer Review Board (MPRB)
SHORT GUIDELINES FOR PREPARATION OF SELF-EVALUATION REPORT
OF HIGHER EDUCATION INSTITUTION

These guidelines were developed by the SPRING project
609528-EPP-1-2019-1-GE-EPPKA2-CBHE-JP (2019-1937/001-001)
participants and were approved by MPRB on Feb. 8, 2021

Introduction

The main aim of the external evaluation by peer review is to provide academic evaluation of the current status, multiple activities, and changes over time of the Higher Education Institution (HEI) as well as to provide recommendations based on the modern concepts of higher education development. The evaluation of Multinational Peer Review Board (MPRB) includes many components and covering 12 standards – areas of assessment. It encompasses not only infrastructure, facilities but also different domains such as vision and mission of institution, governance and management, assess the internal quality assurance system as well as communication and information management. Assessing the potential of a higher education institution evaluates whether the institution is able to further progress and changes by reforming management of financial, material, and human resources.

According to the provisions on Methodology of Multinational Peer Review Board (MPRB) of the Self-Evaluation Report (SER) must reveal the analysis of the main activities of the higher education institution and the perspective of their improvement. The statements in the self-evaluation report shall be based on factual data and documentation. It is very important to highlight and reveal the uniqueness of the higher education institution.

MPRB Methodology suggests introducing the expert group with the latest information: "At least 1 month before the visit to the higher education institution, the higher education institution may provide information on significant changes in the higher education institution.

The activities of the higher education institution are evaluated according to 12 evaluation areas (see MPRB Standards)."

Self-evaluation is a process for evaluating and reflecting on the past and providing a starting point for initiated change in a Higher Education Institution (HEI), thus contributing to the formation of a quality culture in it. It should be noted that self-evaluation is an integral part of the quality assurance system, contributing to the proper functioning of this system.

The self-evaluation aims to address the following strategic issues:

- What does the institution do (mission, vision, strategies)?
- How does the institution do this (process evaluation)?
- How does the institution know that what it is doing is working (outcome evaluation)?
- How is the institution changing in order to achieve the set goals (management of changes)?
- How are the findings of the self-evaluation and the results of previous external evaluations used in decision-making and strategic planning (monitoring of changes)?

The self-report (SER) is the essential document required during the implementation of quality assessment procedures of the Multinational Peer Review Board (MPRB). The main attention of experts should be focused on establishing the effectiveness how the Higher Education Institution (HEI) maintains, monitors, and improves the quality of education offered in the areas of health and related sciences.

The self-evaluation report makes it possible for the team of experts to:

- Get deeper insight how HEI carries out its mission and seeks for their objectives.
- Assess to what extent the HEI fulfils its obligations and responsibilities of the promotion, control, and improvement of the quality of education in the professional fields / majors in health sciences;
- Evaluate how HEI complies with international standards for quality assurance and the best practices of education and research.
- To demonstrate how the practices of HEI governance and management, students' recruitment and certification, community engagement and public communication comply with the criteria of peer review.

Stages of self-evaluation report preparation

The process of SER preparation could be divided into several stages:

Stage 1. The collection of information and the quantitative and qualitative analysis carried out by the self-evaluation team.

Stage 2. Preparation of the text of the self-evaluation summary (for this purpose an editorial group should be formed - representatives of the self-evaluation group, who would prepare the final report using the collected information and the performed analysis).

Stage 3. Discussion of the self-evaluation summary with stakeholders (lecturers, students, graduates, employers, other social partners of the higher education institution) and formulation of conclusions.

Stage 4. Translation of the prepared text (in case primary version is in national language) into English and editing of the translation.

Stage 5. Presentation of self-evaluation report to MPRB.

The SER must review the analysis of the main activities of the higher education institution and the perspective of their improvement. The report shall be based on **evidence, factual data, and documentation.** It is very important to highlight and demonstrate the uniqueness of the HEI. It is also recommended to provide to MPRB the latest information in case when some changes in HEI took place after SER was presented to MPRB. Information on the most recent developments could be provided during the on-site meetings of the staff of HEI with the team of experts in case such information was missing in the SER document.

The format and structure of the self-evaluation report

The activities of the higher education institution are evaluated according to 12 evaluation areas (see MPRB Standards). It is strictly recommended to evaluate each area (evaluation standard) by making the following conclusive statements at the end of chapter describing each area:

- Identify the **strengths and weaknesses** of the area.
- Describe the **evolution and progress** made during last 5–10 years in this area.
- Identify the **strategies, activities for improvement** in the area and the measures proposed.
- Formulate **generalised field conclusions**, linking them with management and other evaluation areas.

- Provide **evidence, factual data, and documentation.**

The text of SER should be presented in a coherent way for each area of assessment, taking into account the criteria and indicators in that area (criteria are not questions to be answered). Areas of assessment include documents or data that are appropriate to analyse in that section. However, it is not recommended to provide excessive sets of documents or data. Higher education institutions are free to examine and provide diverse information reflecting the specifics of its activities, achievements, and good practices.

It is important to show the interaction and coherence of all areas (when assessing each area according to the established criteria and indicators, it is important to reveal the interrelationships in the text). When analysing the areas of study and research (art) activities and the impact on the development of regions and the country as a whole, the results of these areas should be linked to the relevant indicators of the strategic action plan. All information related to the evaluation must be provided before or during the visit.

Volume (number of pages). It is recommended that the length of the self-assessment summary should not exceed 60 pages not including appendices.

Style. It is advisable to avoid long descriptions. In cases where the strategy or structure of the institution requires a description, reference may be made to individual documents, which are annexed to the self-evaluation report or are available online. Infrastructure, committee structures, schemes of quality assurance processes may be provided.

The self-evaluation summary must be prepared in accordance with the assessment areas defined in the MPRB Quality Assurance Standards for Peer Review. It is also useful to provide future plans or strategic decisions that are expected to be implemented after the submission of the SER, but they should be based on evidence (documents).

Numbering. It is recommended to number the paragraphs of the self-evaluation report. This is important for experts, who could refer to the paragraph of the self-evaluation report without quoting it, both during the visit, feedback and during writing of the final evaluation report.

Text. The text of the self-evaluation is presented in 1.15-line intervals. Letter size should be 12 points (12 pt.). It is recommended to save the appendices/attachments as separate documents.

Translation. The translation of the SER summary should be of good quality (correct English). It should be noted that all foreign experts will read (with rare exceptions) only the English version of the document, so the quality of the translation must allow for an undistorted understanding of the information and the facts or statements provided.

All essential and important appendices (Mission of HEI; Strategy Plan of HEI development; Regulations for studies etc.) of the SER summary must be translated. HEI also could be asked to translate some parts of other key documents if the panel of experts requests this. Documents in other languages than English or in national language could be acceptable for the panel of experts in case the expert/experts are fluent enough in that language.

Structure of the self-evaluation report

The self-evaluation report summary consists of:

1. Introduction.
2. Analysis of the activities of the higher school according to the assessed 12 areas.
3. Appendices.

Introduction of the self-evaluation report

The introduction to the self-evaluation report summary should provide basic concise information about the higher education institution. This information must describe the scope of the higher education institution's activities and reflect the specifics of the activities. All chapter information should not take up to 2–3 pages. It is suggested to provide information about the group of SER summary, the deadlines set by the higher education institution for the self-assessment.

It is recommended to provide the following statistical information in the Introduction:

- when and how the higher education institution was established (if the higher education institution operates in more than one city);
- the most recent mission, the main governing bodies, a brief description of the institution's specialisation;
- the main data: number of units (broken down by type, e.g., faculties, research institutes, etc.), - number of fields of study and study programmes, number of doctoral programmes,
- number of study fields and study programmes carried out in the higher education institution;
- number of students in the last academic year;
- number of foreign students who came to full-time higher education in the last academic year;
- number of lecturers, researchers, and administrative staff in the last academic year;
- number of doctoral fields;
- number of units (academic and non-academic, etc.);
- other important information.

This is the main part of the self-evaluation report, which should be structured according to the areas/standards presented. Each area on the separate standard is followed by the conclusive part:

A. Strengths and weaknesses.
B. Evolution and progress.
C. Strategies, activities for improvement.
D. Generalised field conclusions.
E. Evidence, factual data, and documentation.

Submission of self-evaluation report to multinational peer review board (mprb)

The higher education institution submits the self-evaluation report in the digital form of the (DOCX or PDF type document) to the provided e-mail address or via e-delivery system or on a computer medium.

The MPRB assesses whether the self-evaluation report summary submitted by the higher education institution has been prepared in accordance with the requirements set out in the guidelines and informs the higher education institution about the necessary corrections within 10 working days from the receipt of the self-evaluation report.

Upon receipt of the information on discrepancies, the higher education institution shall submit a revised self-evaluation report summary to the MPRB no later than within 10 working days from the day of receipt of the information.

At least 2–4 weeks before the visit to the higher education institution additional information on the significant changes in the higher education institution that have taken place after the submission of the self-evaluation report to MPRB may be provided.

PROBLEM-BASED LEARNING IN THE POST-PANDEMIC MEDICAL EDUCATION: SHAPING THE FUTURE

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Abstract. This paper presents several troubling issues with learning, highlighting some moments of problem-based learning (PBL) in the post-pandemic medical education. Based on some initial research as well as institutional and personal experiences, the learning challenges arising in post-pandemic universities are briefly considered. The urgent shift to an online learning environment was sudden and rough with the view of keeping university studies alive. The good news is that pandemic pedagogy catalyses and accelerates fresh insights into online teaching and learning. In the context of PBL, we need to focus on what problems in what form students will solve, and what the group online collaboration will look like under no illusions of free flow. There are no unequivocal answers to newly arising questions, however, to visualise future learning the thirst for sharing light and/or hard experiences has grown significantly and will continue growing.

Keywords: problem-based learning, PBL, post-pandemic education, zoom fatigue, Moodle.

Troubling issues

Seeking to find appropriate concepts to cover the post-pandemic education, I recall Hannah Graham's insight that "hysteresis is a multifaceted concept in volatile times." [1] The university was experiencing 'pandemic hysteresis', which means after changing the state of the system and then changing it back, we are no longer returning to the same place. Therefore, we cannot mechanically go back to studies as we understood them before COVID-19. Is it exclusively a hastily happened digital transformation or something deeper? Does this also mean that previous learning methods have inevitably become outdated and no longer meet changing realities?

Following this train of thought, is problem-based learning still lively and valid in the post-pandemic medical education? Does the slow and thoughtful nature of this learning method not conflict with the experience of urgency, anxiety, and chaos we lived in the COVID-19 landscape? Can our bodies that have been affected by zoom "fatigue and exhaustion" [2] still endure long hours of researching and discussing new concepts, body systems, norms, pathologies, algorithms, etc.? How can isolation, physical distance, and anonymity be transcended so that students experience more communion, emotional closeness, and clearer learner identity in virtual learning spaces? Obviously, there are questions that may have controversial answers, according to diverse and multiple institutional and personal pandemic and post-pandemic experiences. However, to paraphrase Ronald Barnett, the university community needs to be more proactive and involved in in-depth and intensive internal discussions about teaching and learning in general and online teaching and learning specifically. I mean not only to break the 'monotony of traditional lectures' [3] and get caught up in the flow of amorphous small group learning in classes or breakout rooms but to pause and reflect on the new normal reality transforming teaching and learning. What could soothe the learning chaos and sudden flood of distracting online connections?

Virtuality and screens

Starting from the beginning, virtual learning presents unique challenges. There are multiple attempts to reflect on the consequences of COVID-19 for university studies, with a focus on group learning, student autonomy, PBL experiences, etc. These initial results show some successful cases and small disappointments. Lots of excitement, confusion, and concerns about the unforeseen replacing face-to-face learning with virtual learning rise due to the lack of an online teaching and learning experience. We had to gain this experience instantly in a very compressed time frame, without any pre-practice, pre-testing, or slow reflections, just here and now.

What nature of teaching and learning emerged during the pandemic period? In short, some moments are paradoxical. The juxtaposition of the speed of fiber optic internet and the slowness of online learning seems incredible. Some studies show that online learning sessions tend to run slower since students need to pause to allow others time to talk and understand. [4] Eventually, students are also at greater risk of being distracted by extended or excessive screen time and/or home environment. In some groups, the long screen time increased the tendency for passive involvement and reduced questioning. [4] Furthermore, in some cases when the video function is turned off and the microphone muted, students completely disengage from virtual learning while still appearing to be present. [5] The 'impersonal' nature of the virtual learning environment creates "a propensity for detachment and disengagement" [5] making students' self-directness essential. Despite the live, visual connections between remote students and teachers simulating face-to-face learning, for some reason, students get lost, distracted, bored in the online environment, or inadvertently dive into multitasking.

Another line of research intensively focuses on nonverbal overload (i.e., eye gaze at a close distance, a mirror image, reduced mobility, cognitive load) as a potential cause of "zoom fatigue." [2] J. Bailenson raises apt questions that can be applied to explore synchronous online learning experiences: How exhausted do students feel after videoconferencing? How irritated do their eyes feel? How much do students tend to avoid social situations after a remote meeting? How emotionally drained do students feel? How often do students feel too tired to do other things after that? [2] Thus, online learning is associated with physical, emotional, and general fatigue and decreased motivation. Long class hours become even more difficult when they are primitively transferred online. The pandemic experience of universities shows, that if synchronous learning could inject a sense of compulsion, asynchronous lecturing can give online students freedom, especially when they feel overwhelmed by live meetings. Blending synchronous and asynchronous learning seems to be a meaningful choice to improve the online learning experience in a post-pandemic university.

The opposite trend is that online students are studying with their video cameras switched off. This anonymous participation is problematic because face visibility is unreasonably reduced. Therefore, students become invisible to the teacher and to each other. This 'faceless' online learning refers to being just a teacher's voice monologue, combined with students' voice messages, permanently erasing the recognisable meanings that our faces and bodies constantly send to others. Therefore, learning is reduced to the verbal level, when social and emotional aspects of learning are treated as secondary or less significant. Communion, emotional closeness, and clearer online learner identity are severely tested when only voices that are difficult to attribute to familiar faces remain. So, in the near future practices, we need to find a sustainable balance between showing up on screens and hiding behind screens.

The next thought, it is likely that some digital natives may not experience the kind of zoom fatigue and exhaustion experienced by the previous generation of teachers. Online learning provides unique learning opportunities for digital natives. They seem to be obsessed with technology, performing,

and messaging. Since short learning episodes very often are layered with responses to various messages and reactions to photos or images on different platforms, digital natives could feel like fish in the water. However, learning by immersing yourself in endless clicks creates the illusory easiness of learning experienced without diving into deeper layers. Although they crave interactivity and interactivity inspires them every moment, learning inevitably competes simultaneously with other types of interactivities for them. Students' self-regulation should be focused on coping with the various disturbances of being not 'at university'.

Thus, we need to rethink affective, cognitive, and behavioural engagement and disengagement, highlighting the fruitful types of active learning activities in different contexts of learning (e.g., in virtual learning platforms, video conferencing platforms, etc.) by different interactivity modes (e.g., student-student(s), student-teacher, student-content).

PBL as a plural construct

How do these online experiences affect PBL in medical education? Despite all the doubts, PBL has not died. It can dive out of the skin, transform into a barely recognisable one, but remain one of the PBL constellations described or yet unseen by Maggi Savin-Baden's scientific imagination. It is almost clear that there is no one-size-fits-all PBL design, there are constellations and maybe galaxies (if one's imagination can grasp that). Nevertheless, in PBL discourse this method is well-known as a set of flexible, but invariable principles. In this framework, in the middle of the group learning circle as a vivid target is a real and complex problem. Therefore, a small student group tries collaboratively to solve this problem by applying various learning techniques: (re)searching, questioning the obvious superficial and latent elements of the problem, discussing, bridging academic knowledge and practice, creating a shared understanding, and finally constructing a multilayer solution to the problem. Moreover, the tutor acts as a scaffolder of group learning. Ultimately, in practice, PBL relies on the set of learning steps or phases that students go through. From the origins of PBL, a liquid rather than solid learning structure in the form of a small group has been allowed. PBL is constantly splitting up and sticking into new shapes. There are hearing clear voices that PBL as a singular and universal concept has no global future, yet versions of PBL may continue to thrive locally. [6] As a polysemic term, PBL branches out in various directions to remain.

PBL and microlearning

Against this backdrop, how to endure slow learning? Through students' eyes, they need small bites to swallow at the bus stops, waiting for lunch at the café, and elsewhere in noise and distractions. Microlearning looks new and vividly emerging topic in educational discourse and practice. Is it the 'sweet future'? [7] In brief, microlearning is based on microcontent focussing on a single idea or topic in an extremely short learning time (i.e., no longer than 15 min). [8] It has its goals and limitations. But can we chop every complex real-life problem into convenient, one-bite-sized pieces and assemble them back like Lego blocks to construct a solution to the problem? Then the question emerges – how many such small bites will we have to chew and digest? How many times to click and how many files and folders to open? What would virtual learning environments look like? This is an unknown land. My concern is based on the question of where we are moving – towards fragmentation or synthesis. Or from puzzle detail to the whole picture? Is it a faster way?

"The idea that microlearning is a quick and easy way to jazz up a stale learning program is a bit of a myth. Microlearning can actually take just as long, if not more time, to develop and implement." [7]

Microlearning can be seen as part of a larger curriculum. For instance, as a cycle of short lectures to emphasise theoretical accents, refine small conceptual details, figure out the latest research, or review a set of PBL problems. However, the tutorial should remain of classic duration (1–2 hours), because the time for discussion cannot be shortened, especially if students feel hunger for lively interaction

and the problems to be solved are not simplified but complex. And again, then the question arises, how is it with zoom fatigue and online PBL or with blending synchronous and asynchronous learning? How does screen fatigue affect PBL, if it does? How PBL could be realised in a virtual learning environment without losses?

Moodle and PBL

Moodle can be designed to support students and enable activities promoting PBL. Creating modules based on metacognitive, conceptual, strategic, and procedural scaffolding [9] is not the same as sorting deadly boring PDFs, PPTs, or video packages by topic, with quizzes and tests sprinkled in wherever. In the most general sense, many university courses did not utilise Moodle "to its full potential" as a learning resource. [9] Despite the flooding of training, university teachers lacked information about Moodle features and the potential of the specific university version. This lack is due to a number of minor glooms: lack of knowledge or inspiration about how to work with these features pedagogically and within the framework of PBL; feeling quite alone in terms of designing their own Moodle rooms; without passion simply reusing the prior year's module structure; meeting with students at university routinely, therefore, not realising the benefits of using Moodle beyond information dissemination. [9] The investigation of Aalborg University gives us insights into the contradictions of both using Moodle in general and Moodle for PBL.

In practice, university teachers use only a small part of Moodle functionality and have certain preferences. The most common tools being used are quizzes, and workshops, as well as videos, and e-portfolios that can be easily embedded into Moodle. [10] Likewise, the analysis of Moodle rooms (modules) of our university evidenced an iterative structure containing PDFs, PPTs, links to video conferencing rooms, as well as external video resources, and self-tests supporting the subject matter of the course. As in other universities, very few of the Moodle rooms contained external links to student-oriented activities, such as collaborative resources (e.g., online whiteboard, chat forums, google documents). In some cases, Moodle rooms did not display any collaborative tools at all. In contrast to reality, the students appreciate the use of Moodle activities, such as discussion forums, quizzes, and interactive videos. [9] In contrast, passive students do not like active learning methods at all, so static Moodle rooms do not cause them dissatisfaction.

On the other hand, it does not leave an impression that the teachers work very hard, but their efforts bear fruit differently than they expect of themselves. Teacher's reflection after recording an asynchronous lecture:

"I listened to my lecture, and I find it very boring... and I don't know really what and how to do it differently."

What happens and how does it get annoying for the teachers to pre-record and listen to their own lectures? When creating lecture pre-recordings, teachers do not experience contact with students, do not see their faces, and do not hear their replies or questions, so they remain alone with the content. For instance, a reflection from another concerned teacher:

"I sit alone and talk to myself looking at the slides. I don't feel any connection to the students who will listen to me. Will they understand me?"

Tutor functioning is explored in many types (e.g., theoretical, phenomenological, case study, etc.) of research. In the context of PBL, a teacher has to be visible in the physical or virtual learning environment and focused on the students' group learning. This is difficult to achieve, especially if during the pandemic in some cases PBL has been reduced to asynchronous text sharing. How can we activate and inspire collaborative students' activities through Moodle? To begin with, what we are doing asynchronously has its consequences: the thought processes slow down and pass away, and we fall out of the common sense of discourse that normally embraces us when we share ideas synchronously. Unfortunately, most of the Moodle rooms during the pandemic worked as "one-way communication channels". [9] Despite having forums for

sharing messages, students didn't actively interact with the teacher and with each other, hardly asked any questions and commented on others' ideas, and accordingly didn't receive scaffolding and feedback. Therefore, Moodle rooms don't seem to be used at all for collaborative activities both for communication and group learning.

Furthermore, Moodle rooms not only did not use student-oriented or PBL-inclusive activities but also very conventionally presented problems used in PBL. PDFs and Word documents with the cases described clearly predominated. However, real-life problems rarely appear to be consistently arranged and described. Video cases with patient narratives, and test results in various forms (e.g., biochemical, ultrasound, x-ray images, etc.), combining clinical, and diagnostic are more specific to authentic situations. Compared to paper cases, video cases significantly improve cognitive, affective, and overall learning outcomes. [11] In addition, students could create video presentations in advance and post them on Moodle for watching multiple times, and leading feedback from the teacher and other students. Although small-group learning has become a dominant format in medical education, assessment is still largely based on individual performance, as competency-based medical education emphasises individual performance [12]. Moreover, self-assessment and evaluation often remain separate from group learning and often appear only at the end of the PBL cycle, rather than being practiced throughout the process.

Finally, to demystify online PBL practices some fresh findings disclose that the performance of students utilising distant PBL tutorials was lower than that of students participating in the face-to-face approach, as well students felt less engaged in virtual learning [13]. This disturbing data raises the question of where we are making mistakes. The design of the learning experiences, the quality of the content, and the engagement of learners [14] emerge as prime elements universities should work within post-pandemic medical education.

Concluding remarks

In closing, I have outlined the issues we face with online learning and specifically with PBL in the early post-pandemic period. Online learning carries a stigma of being lower quality than face-to-face learning. [15] In this context, online PBL continues to experience setbacks, particularly in relation to virtuality. While technologies have multiplied and diversified the modes in which students can learn and interact, in a PBL course offered through pre-prepared materials, with limited discussions or infrequent feedback as well as in not carefully planned online PBL sessions, the risks of unacceptably poor learning experiences are very high. With varying levels of digital fluency and practice of live and asynchronous teaching and learning in a virtual environment, to bridge the gaps university teachers also need scaffolding. It is clear, that meaningful online learning requires a student-centred design. Now we are still emerging with simply 'knowledge in pieces', rather than a common pedagogical framework for online teaching and learning.

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SET UP OF THE OBJECTIVE STRUCTURED CLINICAL EXAMINATION IN UNDERGRADUATE MEDICAL EDUCATION: THE EXPERIENCE OF TBILISI STATE MEDICAL UNIVERSITY

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Abstract. The Objective Structured Clinical Examination (OSCE) is used increasingly in undergraduate medical education to assess clinical competence. Reforms aimed at modernising medical education were carried out at Tbilisi State Medical University (TSMU), Georgia. One of the important issues was the introduction of the OSCE. Good set up for an OSCE is vital for both those running the exam and for students. The purpose of this article is to describe the path TSMU has taken in implementing the OSCE and the impact of these changes on medical education. We described the introduction and development process of OSCE in the Department of Clinical Skills and Multidisciplinary Simulation (CSMS) of TSMU from 2012 to spring 2020 (before the pandemic) with a review of the relevant literature.

Keywords: OSCE, Medical Education, Clinical skills.

Introduction

Miller's 4 level (knows, knows how, shows how, does) pyramid of assessment provides a framework for assessing clinical competence in medical education and can assist clinical teachers in matching learning outcomes with expectations of what the learner should be able to do at any stage. The objective structured clinical examination (OSCE) reaches the third level of this pyramid [12].

OSCE was firstly described half a century ago by Harden. It was compared with already existing methods (long case and short case examinations) of assessing clinical performance. Since that time this format of exam has been studied by researchers, and according to the literature it is accepted by students and faculty members [3], it has acceptable validity and reliability [3]. OSCE now is frequently used for summative (endpoint) and formative (ongoing) assessment in medical education including paediatrics [3], obstetrics and gynaecology [4, 13], and other specialty areas [5–7].

Today it is already well known that OSCE is the best way to assess clinical skills performance and competence. OSCE can eliminate subjectivity, as it is based on the principles of objectivity and standardisation. In other words, assessment using OSCE format is fairer and more objective than other formats of assessment as all candidates are placed under the same conditions because they are assessed using exactly the same stations, with the same standardised marking sheets, where all steps of tasks that should be performed are ranked and students get marks for each step on the mark scheme that they perform correctly, all candidates are given the same timeframe. So-called "multiple biopsy" (assessments at several stations by different assessors) increases objectivity as well. OSCE is useful for the assessment of and for learning, but unfortunately it is frequently abused and performed badly. Ideally assessment

should drive learning and guide students in their study. So, a well-designed OSCE can drive learning, and therefore, can have a positive educational impact. Of course, it has its disadvantages. A major obstacle of OSCE is its high cost. Which includes salary for invited examiners, administrative costs etc. [14]. External factors can contribute towards poor performance in an OSCE [8]. OSCE can become exhausting for staff [9].

Over the past decades, Georgian medical education has undergone many changes to meet global standards and meet modern challenges. In 2011 standards for undergraduate medical education in Georgia were based on learning outcomes identified by TUNING/ MEDINE, where 12 competencies were described in total. Current standards are based on World Federation for Medical Education 2015 standards (Directive 2013/55EU of the European Parliament and of the Council) which was Updated in 2020. Current Sectoral Characteristics in Medicine Includes 13 competencies. Tbilisi State Medical University (TSMU) responded in several ways and now is implementing the process of the development of new curricula, the introduction of modern methods of learning and the introduction of the new methods of assessment. The call to enrich the curriculum with new teaching methods which will ensure to fill the existing gap between reality and classrooms led to the inclusion of Simulation Based Learning (SBL) in the undergraduate curriculum of TSMU. So, since the 2012–2013 academic year the Clinical Skills and Multidisciplinary Simulation Department (CSMS) of TSMU offers courses for various faculties of the TSMU using SBL. Among them are three compulsory training courses for students of the 2nd, 4th, and 6th year of the Faculty of Medicine, where they are given the opportunity to learn various clinical skills, procedures and manipulations using manikins and simulators and gain 10 credits totally. Out of 13 competencies provided according to the sectoral characteristics of medicine, 2 competencies can be implemented in the centre, namely #3 – emergency medical care (first aid and resuscitation) and N5 – practical procedures. Assessment, which is a process of gathering and judging evidence in order to decide whether "a person has achieved an agreed standard or outcome" (AMEE) is an essential part of learning and teaching. One of the important issues of reforms aimed at modernising medical education at TSMU was the introduction of the OSCE , as it is the gold standard for practical and behaviour skills assessment. The OSCE have been introduced for the first time in Georgia at TSMU.

Though the underlying principles of OSCEs are common to all medical schools, there are variations in how OSCEs are delivered. Globally there is no standard operating procedure for running OSCEs. At the same time, sometimes not all assessors are prepared for the assessment, with 38.5 % never having received any formal training on assessment [10]. OSCEs should be managed at the university's simulated clinical skills area so all students are exposed to the same environment [11]. The introduction of the OSCE is a challenging process requiring a considerable amount of theoretical and practical knowledge [1]. So, the Department of CSMS has started a difficult and exciting way of introducing this format of exam in 2012.

This article describes how the OSCE was introduced at CSMD of TSMU. For those who plan to introduce such format of exam, this article, in our opinion, contains valuable recommendations for conducting OSCE, as it will help accelerate the adaptation process and reduce trial and error cost inefficiencies. Even for those who already use OSCE, our article can give new ideas or become an encouragement for the exchange of ideas. Sharing experiences at all levels of applying OSCE will help all of us to improve the quality of this type of exam.

The path taken by CSMSC of TSMU in implementing the OSCE

TSMU can be considered a pioneer of the implementation of the OSCE in Georgia. A pilot version of the OSCE was carried out in 2012.

It was decided that the first OSCE would be initiated with 4th-year students of the Faculty of Medicine in Obstetrics and Gynaecology.

The curriculum was renewed and revised by the Department of Obstetrics and Gynaecology of TSMU with the support of The United States Agency for International Development, John Snow Institute and World Health Organization as the clinical tasks chosen for the OSCE should map onto the learning objectives of the course and the candidates' level of learning. The content of an OSCE, was carefully structured to ensure that all parts of the curriculum as well as a wide range of skills are covered, that all tasks at stations are relevant and realistic and correlated with learning outcomes. Banks of clinical situations were developed. It was decided to have seven so called active stations and one rest station. 6 minutes were assigned for each station. Marking sheets were created and weighted to each component and minimum standard required to pass were established.

During the pilot OSCE in Ob-Gyn it was revealed that time given for one task was not enough. Thus, the task on that station was changed a little bit.

CSMS Department of TSMU was additionally equipped with gynaecological simulators, so that students were properly prepared for their exam.

Over time it has become a routine for the department. However, each time the Department of CSMS prepares for the exam in advance so that the actual exam days can go smoothly.

OSCE personnel including examiners, simulated patients, circuit coordinators, registers (participating students and distributing their badges) should be recruited and prepared well in advance. Different type of trainings should be scheduled for them. For example, it is not easy to schedule such trainings for examiners as they are busy clinicians and need advance notice to enable them to attend trainings. It is also quite difficult to call several clinicians from one and the same workplace on exam day (as they often work together in university clinics), so this must be agreed on in advance. On the exam day it is essential that there are persons on site who will replace the examiner in case of an emergency in order for the exam to run smoothly. Administrative staff must be instructed to get familiar with OSCE specifics. So administrative issues must be also taken into consideration as this requires central co-ordination.

One of the important questions is printed materials, which are quite large, as they include the following: instructions for students, simulated patient scenarios, marking sheets, signs, flyers for students etc. This material is sorted (academic part, flyers, and signs) and is printed 2–3 days in advance. Rooms (stations) must be numbered, other signs (so that everyone can easily find their way on the day of the exam) must be placed the day before the exam. Scenarios, tasks for students, marking sheets should be placed several minutes before each round of the exam. Here, great care is needed not to confuse the materials of different stations.

Everything necessary for completing tasks in the exam, including equipment, materials, manikins, is indicated in the special form "List of necessary equipment." All listed simulators and materials shall be transported to the station. The day before the exam, all stations should be checked to make sure that all manikins, materials, and necessary tools are in place. Each class (converted into a station during the OSCE) is equipped with a video recording system. Thus, observers can see OSCE performances from the control room, and if necessary, OSCE recordings are available for students and examiners to review.

It is very important to inform students, for this the interested departments and the administration of the university organise a meeting with them 10–14 days before the exam day to give them general information about the number of active and rest stations, time in and within stations, what to bring to the exam (medical gown, phonendoscope), and answer their questions.

As a result of collaborations between the Department of Obstetrics and Gynaecology and the CSMS Department, beginning in the 2013–2014 academic year, the obstetrics and gynaecology exam is held at the end of each semester for year 4 students. Half of the fourth-year students complete the Obstetrics and Gynaecology module and the Clin-

ical Skills module, and take the exam in the fall semester, respectively, and the other half at the end of the spring semester. From the 2013–2014 academic year to the pandemic, 13 examination sessions were held. The exam lasts 3 days and the average number of students who take the exam each time is 264 (SD = 14.6).

Already achieved results and plans for the future

The introduction of the OSCE in Obstetrics and Gynaecology yielded the following results:

1. Syllabuses of Department of Obstetrics-Gynaecology, Paediatrics, Internal Medicine and KMS have been revised/updated. The Clinical Skills course of the CSMS Department has become a mandatory component of the abovementioned disciplines (Obstetrics-Gynaecology, Paediatrics, and Internal medicine).
2. The summative assessment for all above modules is performed in the OSCE format. The number of stations for year 4 and year 6 students has increased and equals 12 stations. The CSMS centre is designed in such a way that there are two circuits of 12 OSCE stations, that is, there are 12 duplicate stations. While this increases throughput, it also requires more human resources in one period of time.
   - Year 4 students have a 12-station OSCE twice during one academic year, namely half of them in Obstetrics-Gynaecology in the autumn/fall semester, and the other half in Paediatrics and vice versa in the spring semester.
   - At the end of the 12th semester Year 6 (final year) students take the final exam in Internal Medicine in the format of a 12-station OSCE.
3. The summative assessment of year 2 students and for all compulsory and elective courses offered by CSMS are carried out in the OSCE format. In these cases, the so-called mini-OSCEs with 4 stations are carried out.
4. When the CSMS department was just beginning to conduct exams in the OSCE format, the call was carried out using a stopwatch and a loud manual bell. The electronic timing program is now used. The system allows you to select the room (station), the time required to complete the task and move from station to station. At the selected stations in the selected time interval, the operator's voice is heard – "Please enter the station" or "Your time is up, please leave the station". Part of this system are timers placed on the doors of all rooms that show the allotted time and also have red and green lights. Green means you can get in and out and red means you can't get in or out of the station.
5. The department regularly conducts a survey of students and of academic staff and these well-organised examinations are highly appreciated by both.
6. A study conducted by the University Quality Service showed that the introduction of the OSCE has had a positive impact on the quality of university teaching in general
7. The OSCE was successfully implemented in TSMU, it became an example for other medical schools and became widespread in the field of undergraduate medical education in Georgia. The TSMU conducts OSCE training for those who plan to introduce the OSCE or want to improve the existing OSCE in their organisations.

A vision for the future

In all directions, including academic and organisational issues, the following steps are planned to improve the quality of OSCE:

1. Stations, especially in the case of the year 6 OSCE (final), should be organised so that they adequately cover a wider range of clinical competencies. Including communication skills, professionalism skills, history taking skills, physical examination skills, clinical-reasoning skills, and technical skills. Stations should be representatively and systematically sampled from the entire range of learning outcomes of the course. In this regard, the academic staff of the departments participating in the OSCE should be more familiar with the specifics of OSCE blueprinting. Enriching the clini-

cal case database is also important. A lot of work is ahead in this direction, which also includes joint working meetings of appropriate departments.

2. It is necessary to modernise and enrich the necessary equipment. CSMS classrooms/ stations should be set up similarly to clinic rooms.
3. It is planned to replace the marking sheets with tablets, i.e., a complete transition to an electronic system. It requires a lot of effort from the Technical Service of the CSMS Department, the Technical Service of the University, and the concerned academic staff.

As they say, there is always room for improvement. The CSMS Department's efforts are aimed at ensuring the continuous improvement of the OSCE quality, taking into account the reliability, validity, educational impact, and cost efficiency of the test. We expect that thanks to these efforts, TSMU will continue to be the leading OSCE centre in Georgia. Sharing our experience is important as knowledge and experience is seen as the most important assets for sustainable success.

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IMPROVING THE QUALITY OF MEDICAL EDUCATION AT GRODNO STATE MEDICAL UNIVERSITY THROUGH INTERNATIONAL ACCREDITATION EXPERIENCE

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Abstract. The article presents an analysis of the effectiveness of Grodno State Medical University (GrSMU) activities as part of the implementation of the Erasmus KA2 project "Setting peer review instruments and goals for medical (health) education" / SPRING to improve the quality of GrSMU performance. The University has demonstrated full compliance with the World Federation for Medical Education (WFME) criteria, as well as continuous improvement in the quality of activities through international accreditation experience, which was confirmed by the results of the SPRING follow-up mission to GrSMU. Particular role in this belongs to the University's understanding of the need for continuous and sustainable improvement of its activities. Such awareness is formed most effectively through a self-evaluation procedure. The stage of institutional self-evaluation highlights the strengths of the University, determines the positions for improvement, and makes it possible to identify some areas of the University performance that did not have a clearly defined status of significance before the moment of accreditation. It can be reasonably argued that the effect of the self-evaluation procedure is especially significant when this procedure motivates the University staff for further development. A special feature of the accreditation process for GrSMU within the framework of the project was that the University was the first among the universities of the consortium to complete the accreditation cycle, including the follow-up mission. Under the COVID-19 restrictions, and then due to certain geopolitical challenges, the University had to test the accreditation procedure at all stages online for the first time. At the same time, the quality of the procedure has not suffered, as evidenced by the conclusion of an independent accreditation agency on obtaining a certificate of conformity in 2021 for a period of 5 years.

Keywords: international accreditation, self-evaluation, education quality assurance, SPRING project implementation.

Introduction

In Belarus all educational institutions operating under the Ministry of Health organise their activities aligned with the national legislation and are obliged to undergo national accreditation. Until recently, this procedure has been sufficient to ensure the quality requirements for the export of educational services by institutions implementing educational programmes of the first and second stages of higher medical education.

At the same time, in 2015, the procedure for Belarus joining the European Higher Education Area (EHEA) was formally completed. Being a full EHEA member, Belarus is introducing the EHEA unified performance assessment tools into the national system of education. One of these principles is to guarantee the quality of medical training that meets the standards of the World Federation for Medical Education (WFME). For all levels of medical education, the WFME has developed standards that are publicly available on the WFME website [1].

It should be noted that the national legislation for the employment of medical graduates in some countries, e.g., the United States,

envisages strict compliance with the requirement [2]. A less rigid, but still determined policy of requirements for the quality of training in healthcare is being implemented in the European Union countries [3].

One of the requirements starting from 2022-2023 is the inclusion of a higher educational institution (HEI) that a foreign graduate graduated from in the list of medical schools accredited according to the WFME criteria by one of the accreditation agencies that received permission from the WFME for expert activities [3]. At present the majority of the medical schools in the developed countries worldwide are externally accredited [4].

Such a policy for education quality assessment is being implemented by the WFME in accordance with goal 1.1. Global Strategy of the World Health Organization (2016) Global Strategy on Human Resources for Health: Workforce 2030. According to this goal, by 2020 all countries were supposed to have "established accreditation mechanisms for health training institutions" [5].

Thus, in modern conditions, the export of educational services in healthcare by the HEIs that have not been accredited according to the WFME requirements becomes impossible.

Until 2021, none of the universities in Belarus had a confirmed status of international accreditation. At the same time, building up the potential for the export of educational services is one of the priorities of higher education in Belarus [6].

The purpose of this study was to illustrate the improvement of the quality of medical education at Grodno State Medical University (GrSMU) through international accreditation experience.

Discussion

1. Prerequisites for the process of international accreditation at GrSMU

In 2021, GrSMU became the first among all HEIs in Belarus to start the international accreditation procedure.

This decision was preceded by certain historical experience [7], as well as the achievements of the University: the international competition "Leader of the Year 2019" (winner in the nomination "Educational Services"); "Best Exporter 2019" (organised by the Belarusian Chamber of Commerce and Industry – winner in the nomination "Education"); Grand Prix of the International Business Award "Leader of the Year 2020" in the nomination "Services in the field of education" (the leading university: it was in the premises of GrSMU that the first university clinic in Belarus was organised).

The international accreditation procedure was completed successfully: GrSMU received the status of Belarusian first HEI in the field of medicine, which confirmed the compliance of its performance quality with the WFME criteria. The certificate was awarded to the University for the maximum possible period of 5 years.

This achievement is evidently connected with GrSMU participation in the ERASMUS+ KA2 project – Cooperation for innovation and the exchange of good practices, Capacity building in higher education "Setting Peer Review Instruments and Goals for Medical (Health) Education" (SPRING).

One of the SPRING project objectives was to raise the awareness of partner universities of the peer review process as an effective tool for ensuring ongoing improvements in the academic and administrative fields at medical HEIs in target partner countries and beyond; and to assist medical HEIs in target regions in effective preparation for international accreditation.

By the time of GrSMU entering the accreditation process, the SPRING project was implemented by 40 %: instructional workshops for the academic staff and administration of GrSMU were conducted by the international experts from the employees of the SPRING project partner universities, as well as by the invited experts; the requirements for the self-evaluation report (SER) activities of the University were elaborated; a schedule for instructional peer review baseline mission was designed.

2. Specifics of the SPRING instructional international accreditation of GrSMU

2.1. Preparatory stage

In the 2020–2021 academic year, as part of the SPRING project implementation, three

distance learning workshops were held for GrSMU staff: "Ensuring the quality of medical education and education in the field of public health and healthcare" (November 3–4, 2020) and "Training academic and administrative staff in peer review and international accreditation" (December 1–15, 2020, and January 14–15, 2021), in which more than 40 university employees took part. During the workshops, intensive online training was organised, with lectures, role-playing games, working in small groups (from three to ten people). The groups were mobile, the composition of the groups changed during the day and included representatives from different partner universities and different countries, each of the participants had an opportunity to act as both a student and the rector of an accredited university. The organisers were the Lithuanian University of Health Sciences (Kaunas, Lithuania), the Medical University (Sofia, Bulgaria), Batumi International University (BAU, Batumi, Georgia).

2.2. Stage of self-evaluation of GrSMU performance quality

During the SER preparation, the working group collected and analysed relevant data characterising the overall GrSMU activities over the past five years (2016–2020). Self-evaluation of educational programmes, faculty, educational and other resources was carried out.

Though being instructional, self-evaluation performed as part of the SPRING project implementation was carried out according to the WFME criteria. At the same time, the SPRING instructional SER included GrSMU performance analysis according to 12 standards (which is three standards more than those required by the agency that accredited GrSMU) and was compiled in accordance with a different list of checkpoints. Thus, both the list of standards and the checklists for them may differ at large in the requirements of various international accreditation agencies, but all of them shall meet the WFME criteria.

The self-evaluation process took about two months of active and strenuous work on a comprehensive self-assessment of GrSMU activities, followed by SER translation into English, the development of an appropriate glossary and the supporting evidence base set out in the annex. It should be noted that the volume of annexes significantly exceeded the volume of the SER itself, despite the fact that online access to the evidence was used to the maximum.

It has been proved that GrSMU carries out its activities in accordance with the University Statute, which sets out the Mission, Vision, Strategic Objectives, reflecting the place and role of the University in the socio-economic, strategic, scientific, and cultural development of Belarus. The chosen policy and development priorities allowed GrSMU to take a leading position in the field of higher education in Belarus and successfully achieve the main goals, as well as to train specialists for the healthcare system. The organisational, functional and personnel structure correspond to the Mission, Goals and Strategic Objectives of the University. GrSMU organisational and managerial structure is organised in accordance with modern guidelines and rules for effective management.

The content of the educational programmes of the compulsory component corresponds to the modern level, and elective courses reflect innovations and the requirements of the employers. The University monitors the quality of the development of educational programmes in accordance with the established criteria and ensures constant monitoring and improvement of the educational services provided. Particular attention is paid to the practical component in the educational process, the acquisition of clinical competencies by students. For this purpose, the University Clinic was organised the work of which is aimed at strengthening the practice-oriented student training, the development of simulation technologies is being effectively carried out, and the use of an objective structured clinical exam (OSCE) is being introduced.

GrSMU provides all the conditions necessary for the students' effective mastering the educational programmes that satisfy their interests and needs, ensuring this activity with appropriate resources (library, consulting, information). A Psychological Support Service

for students has been organised, opportunities for personal growth and development of young people have been provided.

The high level of the academic staff contributes to the development of graduates with sufficient knowledge and training skills needed in the labour market.

GrSMU conducts purposeful work on the development of international cooperation. Particular attention is paid to academic exchange programmes, the development of full-fledged scientific cooperation. Scientific research conducted by the University demonstrates dynamic development, compliance with high scientific qualifications.

GrSMU has developed effective financial management. Over the past five years, there has been a stable level of income for its employees.

Thus, the main GrSMU activities reflect constant positive dynamics of quantitative and qualitative performance indicators: the availability of qualified personnel, high-quality educational programmes, internationalisation of education, which directly affects its reputation in the national and international markets. Constantly updating and improving all processes in accordance with the achievements of medical science and practice, GrSMU effectively implements the adopted strategic goals.

The self-evaluation procedure further united GrSMU staff, allowed to evaluate actual achievements, determined the direction of improvement activities, integrated all initiatives, supported internal and external exchange of positive experience and increased responsibility for the performance outcomes and the results of accreditation.

Particularly noteworthy is such an indirect University accreditation result as the development of a corporate spirit: the intense work of the faculty, administration, students, graduates, employers, and other stakeholders contributes to the formation of a strong organisational culture, business climate in the team of University personnel. Transferring information to the external environment enhances the image of the University not only in the country, but also abroad.

2.3. Instructional GrSMU accreditation as part of the SPRING project

Instructional accreditation took place on June 2–3, 2021, in an online format due to COVID-19 restrictions. GrSMU became the first member of the project consortium to enter this project stage. The schedule of the instructional on-site visit was based on the requirements of the WFME for international accreditation of medical schools. For two days, on June 2 and 3, 2021, interviews were held by the experts with target groups of GrSMU representatives: the top management of the University, deans, members of the University Council, the SPRING project working group and the SER developers, students, alumni, academic staff of GrSMU academic departments and curriculum developers, as well as an online meetings with employers and social partners.

During the accreditation, the experts made suggestions and recommendations; an action plan was prepared to implement the suggested improvements. Some of the recommendations were consistent with those made by the International Accreditation Board.

It should be noted that, in contrast to the standard procedures for national (internal) accreditation, international accreditation has identified new areas of GrSMU activity that should be included in the analysis during institutional self-evaluation, such as community involvement; information management system; public communication. Despite the fact that all these areas were somehow developed at the University in accordance with the requirements of time and globalisation, the self-evaluation process in terms of WFME standards made it possible to identify them as separate important priorities more clearly for a medical university.

Self-evaluation identified strengths and weaknesses in the implementation of the goals and objectives defined by the Mission and the Strategic Development Programme, evolution and progress made, strategies and improvement activities. For example, it was emphasised that during the COVID-19 pandemic, the distance form of organisation of the educational process was provided and the system of advanced training of employ-

ees was maintained. GrSMU developed new distance learning forms and evaluation of its outcomes (certifications), ensuring the quality of the educational process in the conditions of the COVID-19 pandemic. Despite the COVID-19 pandemic, the professional development of the staff was maintained.

However, it was found that despite such potential, community participation and sponsorship in the financial sustainability of GrSMU is limited, additional sources of research funding are required. In addition, the problem of limited opportunities for persons with disabilities shall be properly addressed as well.

GrSMU provides monitoring and continuous improvement of the management of the goals of educational programmes, learning outcomes and their compliance with the programme, develops and implements new educational standards integrated into the European Education Area. At the same time, the requirements of the WFME make it necessary to continue the harmonisation of national standards with international ones. It is necessary to increase the coverage of students and faculty with exchange programmes. This will facilitate the exchange of experience and the assimilation of advanced approaches used in the world for learning and teaching at a medical university. It is necessary to develop measurable unified approaches to the analysis of the profile of the student body, an information system of career pathways for students and other categories of learners. Special attention within the framework of medical education programmes abroad is given to postgraduate education – residency, Master's, and Doctoral studies. These stages of continuous medical education have received development and impulse for improvement in Belarus as well.

2.4. SPRING project follow-up mission to GrSMU

The SPRING project follow-up mission to GrSMU took place during the period of acute geopolitical challenges, which significantly limited the possibility of its successful implementation. Despite this, the University retained its position as the first university to successfully pass this stage of the project implementation. The follow-up mission took place online. GrSMU was the first to test similar format and disseminate this form of organisation to a partner university from Minsk.

An analysis of the activities carried out in preparation for the follow-up mission showed that the focus on the recommendations of international accreditation allowed the University to achieve significant progress. For example, the introduction of new educational standards that meet the WFME criteria, the development of new curricula in accordance with them, designing a new academic building of the University, taking into account the need for inclusion for disabled persons, the development of practice-oriented education, and others.

This progress illustrates the improvement in the quality of activities in a number of components, and consequently the improvement in the quality of medical education provided by GrSMU.

Conclusion

Thus, GrSMU has demonstrated full compliance of the quality of activities with the WFME criteria, which was confirmed by the awarding accreditation certificate in 2021 for a period of 5 years, as well as the continuous improvement of the quality of activities through international accreditation experience, which was confirmed by the results of the SPRING project follow-up mission.

A special role in this belongs to the University's understanding of the need for constant positive changes and improvement of its activities. This awareness is formed most effectively through an effective self-evaluation procedure, which, in our opinion, should be given special attention. The stage of institutional self-evaluation is an important and obligatory stage of the international accreditation procedure. This stage highlights the strengths of the University performance, and at the same time, identifies positions that need to be strengthened and improved. It also gives unexpected results, making it possible to identify areas of the University's activities that did not have a clearly defined significance before the moment of accreditation. It can be reasonably argued that the effect of

the self-evaluation procedure is especially significant when this procedure motivates the staff for further development.

Specifics of the SPRING project accreditation process for GrSMU was in the fact that the University was the first among the universities of the consortium to have completed the accreditation cycle, including the follow-up mission. Under the COVID-19 restrictions together with geopolitical challenges, the University had to test the accreditation procedure at all stages online for the first time. At the same time, the quality of the procedure was not affected, which is confirmed by the final conclusion of an independent accreditation agency.

In general, a qualitative assessment of the activities as part of the SPRING project implementation made it possible to conclude that they are highly effective in improving the quality of GrSMU performance.

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MANAGEMENT OF MEDICAL TECHNOLOGIES IN THE REPUBLIC OF MOLDOVA – THE BASIC COMPONENT OF SAFETY, EFFICIENCY, AND QUALITY OF MEDICAL SERVICES

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Abstract. The evaluation of global experience in the field of medical technologies revealed that high-performance medical devices represent an indispensable component in the prevention, correct diagnosis, and treatment of diseases that occupy the first positions in the structure of mortality and morbidity. Their effective use supposes, as a matter of priority, to increase the number of cost-effective and qualitative investigations and treatments. The maintenance, verification, and management of medical devices have become a priority in the health policy of many states, argued by studies that through coherent policies in these fields, the cost/efficiency ratio of the use of advanced medical technologies is maximised, increases patient safety and, last but not least, increases the quality of the medical services.

Keywords: medical devices, medical technologies, biomedical engineering, maintenance of medical devices, regulation, Republic of Moldova.

Introduction

Thousands of years ago ancient civilizations used medical instruments such as forceps, knives, scalpels, saws, lancets, needles, etc. for medical procedures. The formation of medicine as a science in the 17th century contributed to the spread of medical devices, especially through universities, and advances in the fields of medicine permanently supported the development of new medical instruments. The 1800s marked the revolution in medical devices, with therapeutic and medical inventions contributing inestimably to the formation of modern medicine. The 19th century is characterised by the introduction of the stethoscope, the ophthalmoscope, the electrocardiogram, the hearing aids, the hypodermic syringe, and the kymograph onto the medical market. With the use of new materials approved by medicine, especially steel, and its alloys, the design of medical devices is also evolving. In the 20th century, we are witnessing the exponential development of medical devices (e.g., cardio defibrillators, hip and knee prostheses, laparoscopes, dialysis machines, infusion pumps, insulin pumps, balloon catheters, inhalers, cardiovascular devices, respiratory devices, ventilators, and implants, etc.) [1].

What is a medical device (MD) today? A medical device is an instrument, apparatus, implant, machine, tool, in vitro reagent, or similar article that is intended to diagnose, prevent, alleviate, treat, or cure disease or other conditions and, achieves its purpose by acting physically, structurally, or mechanically.

The growth of the medical device market in the mid-20th century required specific regulation of medical devices to ensure patient safety and public health. Special regional, and state requirements were introduced for the marketing of MD, and in the 1990s, we witnessed the first harmonisation of the exist-

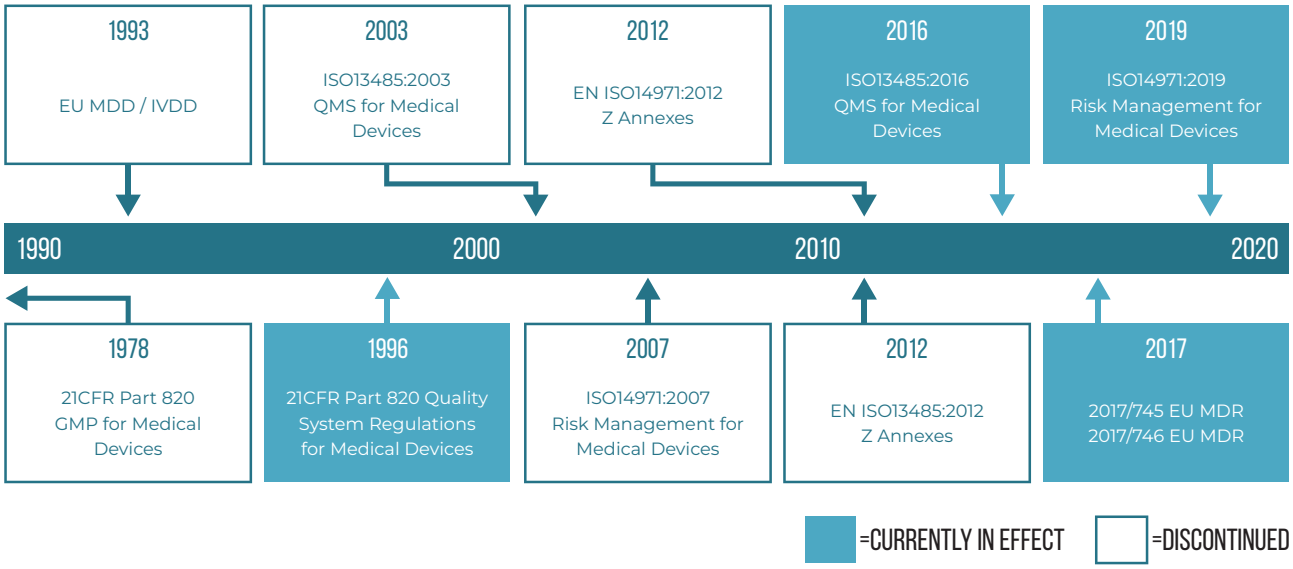

Figure 1. Evolution of medical device standards [1]

ing broad spectrum of national and regional regulations and requirements by introducing conformity assessment procedures, with the collaboration and representation of institutions and specialists in the field worldwide. Regulations and standards continue to evolve in line with changes in technologies, the ongoing need for global harmonisation, and the imperative needs of beneficiaries. The evolution of the historical and current applicable standards is shown in Figure 1.

We also witnessed exponential growth in the production of MD. The global MD market is estimated to grow from USD 495.46 billion in 2022 to USD 863.40 [2] billion by 2030 (Figure 2). The US is the largest region in the global MD market, accounting for 39.7 % of the total in 2020. It is estimated that the fastest growing regions in the medical device market will be the countries of South America and Africa. The European medical technology market is estimated at roughly €140 billion in 2020. In Europe alone there are currently around 33 000 companies producing medical devices/technology. The highest number of them are based in Germany, followed by Italy, the UK, France, and Switzerland [3].

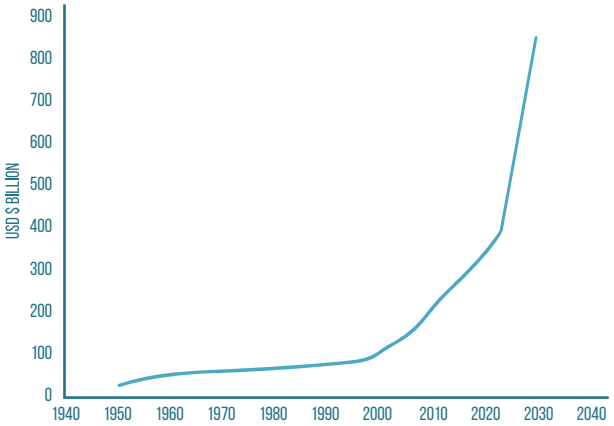

Figure 2. Global Medical Device Market Growth. Inspired by [1].

The evolution of MD shows that 10 years ago, about 50 % of all diagnostic and treatment methods used today did not exist, the development period of DM being estimated on average from 2 to 3 years, and the period of moral obsolescence of DM (from production and launch on the market) is estimated at 5–7 years. The significance of medical technologies has become even more pronounced and recognised with the need to combat the COVID-19 pandemic.

The evaluation of the global experience in the field of health demonstrated that high-performance MDs represent an indispensable part of the medical act in the process of prevention, correct diagnosis, and treatment of diseases. Their effective use presupposes, as a matter of priority, increasing the number of investigations and cost-effective and qualitative treatment. Equipping

medical institutions with high-performance MD is a priority at the national and institutional levels. We also appreciate the importance of MD by the fact that since 1980 in developed countries there has been a 58 % decrease in the number of patient days spent in hospitals due to medical technologies [4].

Good international practices demonstrate the need for the operative and continuous implementation of research results, and new innovative technologies with the potential to improve medical services offered to the population. Effective technologies associated with relevant health improvements create an ongoing challenge for health systems, as their most effective application requires increasing identification of financial and human resources for the health system. Obviously, the increasing costs of new technologies require the optimisation of the evaluation and management of MD, but also of the available resources, and the most effective technologies must be promoted taking into account organisational, ethical, and societal issues in particular. Adequate management is an indispensable condition [5, 6] for ensuring a high level of safety, in some cases also security, but also the performance of medical devices. Respectively, ensuring the uninterrupted functionality of the health system, increasing the quality of medical services, and the degree of satisfaction of the beneficiary, are dependent on the technical-material basis, the professional competence of the personnel involved, as well as the quality, efficiency, and safety of medical devices. To improve the availability of innovative healthcare technologies such as medicines and certain medical devices to patients in the EU, Regulation (EU) 2021/2282 on Health Technology Assessment (HTAR) [7] was approved. This regulation aims to contribute to an efficient use of resources, strengthen HTA quality in the EU, reduce duplication of effort for national authorities and industry, facilitate business predictability and ensure the long-term sustainability of EU HTA cooperation. In addition, it led to the approval in May 2022 of an implementation plan until 2025 [8].

Health technology assessment provides evidence-based and up-to-date information for policymaking on the use of technology in health services. Periodic health technology assessment thus acts as a mediating mechanism between policy, research, and implementation domains, providing a problem-oriented systematic overview of research needed by both producers and users. This allows the adoption of a high-quality and current standard in the medical service system

Estimates carried out by the World Health Organization (WHO) have shown that, along with the imperative of the annual allocation of billions of dollars to complete the DM park, most countries appreciate the primary importance of Medical Technology Management (MTM) as an integral part of public health policy. Thus, WHO estimates of the situation in medical and sanitary institutions in developing countries indicate that approximately 50 % of medical equipment does not work because it is incorrectly used and maintained – a situation with serious consequences for the services provided and patient care. For these reasons, WHO recommends the existence of a national policy on MD Management, which includes the provision, ensuring the maintenance, verification, and correct use of MD. The training of specialists and the creation of a continuous training system play an essential role in the actuality and continuity of state policy.

The objectives of the management of medical technologies in the Republic of Moldova

The development priorities of the health system in the Republic of Moldova are subordinated to the general objective of improving the health status and quality of life of the population. A healthy population is a long-term investment in the well-being of the nation. The health system is a global and national priority and is one of the 17 primary Sustainable Development Goals promoted by the UN to ensure a prosperous and sustainable society [9]. Ensuring the realisation of citizens' rights to quality medical services remains a priority in the activity of contemporary medical and sanitary institutions. The quality of the services provided is dependent on the technical-material base, including the provision of

medical devices, as well as the professional competence of the personnel involved (the human factor). The importance of medical devices in the medical act has grown considerably with the sharp progress of medical technologies. Thus, taking into account the current experience, it can be stated that the medical act is constituted by 50 % of the doctor's knowledge and skills, and 50 % represents the contribution of medical devices.

MTM within a medical institution represents a set of actions implemented in order to manage resources and processes that ensure the efficient operation of medical devices for the delivery of quality health services:

- Collects basic information about the equipment;
- Plans the technological needs and the allocation of the necessary budget;
- Purchases appropriate models and puts them into operation according to the manufacturer's requirements;
- Allocates sufficient financial and human resources to be used effectively;
- Operates with allocated resources securely and transparently;
- Ensures maintenance and repairs of the DM after putting it into operation;
- Ensures timely replacement and scrapping of unsafe and obsolete parts;
- Ensures professional maintenance of staff according to technological progress to cope with new models of devices put into operation.

The management of medical technologies (health technologies) is a complex and diverse process through the set of components related to the activities related to medical devices and the qualified person responsible for the medical technologies within the institution. The components of MTM are presented in Figure 3. Among the most important stages of MTM throughout the exploitation period until their decommissioning, we note the following:

- MD inventory;
- Planning the necessary MD, consumables, and spares;
- Procurement of MD, consumables, and spares;

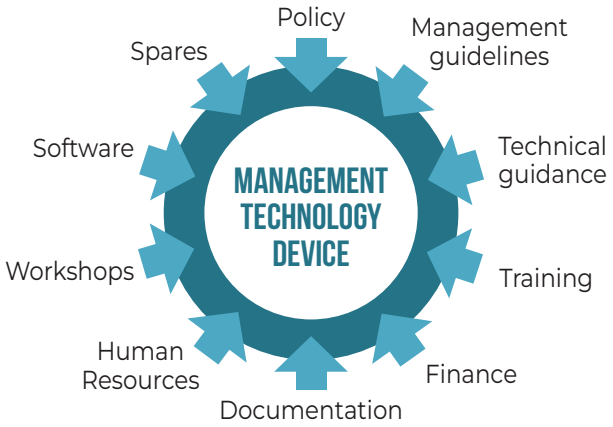

Figure 3. Components of Medical Technology Management

- MD exploitation (operation, monitoring and maintenance);
- Removal from the balance sheet of MD.

The purpose of the development and implementation of the MTM is to:

- Increase the quality of medical services by improving the Management of Medical Devices to ensure a high level of performance and security of medical devices in use in healthcare institutions.
- Reduce the inappropriate use of modern technologies and ensure a continuous and effective availability of appropriate medical equipment for health services;
- Monitor the maintenance activity, correct mistakes, develop specific protocols, and predicting costs.

Management of medical devices in the Republic of Moldova

In 2020 [10] the healthcare system in the Republic of Moldova included 85 hospitals (68 public, 17 private) with 17 168 beds, in which 12 394 doctors work, with a small increase in the last 5 years. On the other side, there was an average of 23 187 medical personnel, decreasing by 10 % in the last 5 years. There are a total of 1062 medical and sanitary institutions that provide primary and specialised medical assistance, of which 439 are public, 615 are private, and 8 are mixed. There are 145 stations, substations, and emergency medical assistance points [10].

In accordance with the provisions of the RM-EU Association Agreement [11], Law no.

102 of June 9, 2017 "About Medical Devices" [12], there is the aim of adjusting the legal framework of the Republic of Moldova to the Community acquis for the implementation of European technical regulations in the field of MD and consumer protection. The signed law stipulates the definitions according to the European Directives with application to MD and establishes that they can be introduced on the market, put into operation, or used only if they are certified, and registered – so that they do not affect the safety and health of patients, users, and other people and the environment.

The limited financial resources, on the one hand, and the increasing requirements of professionals in the field, in order to use high-performance MD, as well as those of the population to have access to quality services, on the other hand, mean that the existing needs are only partially covered. The share of national public budget expenditures for health is continuously increasing, at the same time the cost of MD is becoming higher, while the requirements and possibilities for evaluating their quality and practical safety are missing.

With the support of the Swiss Agency for Development and Cooperation (SDC), the Action Plan for the implementation of the Memorandum of Understanding between the Swiss Agency for Development and Cooperation and the Ministry of Health of the Republic of Moldova regarding the implementation of the National Information Management System Development project of Medical Devices (SIMDM) was developed and implemented [13] focused on including the MD inventory within the IMSP. According to the evaluations carried out through the SIMDM, the public health system had (Figure 4) over 38 thousand DM recorded as fixed assets, the average age being 12.9 years.

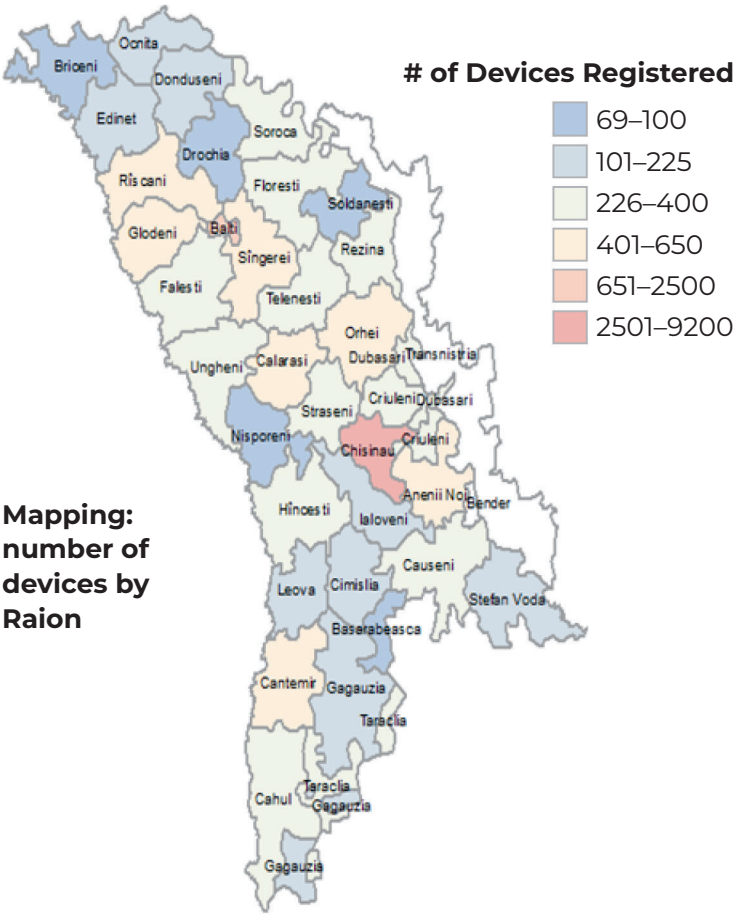

Figure 4. Distribution of MD according to the inventory carried out with the support of the Swiss Agency for Development and Cooperation

Also, with the support of SDC through the PERINAT and REPEMOL projects (Regionalisation of Paediatric Emergency and Intensive Care Services in the Republic of Moldova), the existing procedures related to MDM at the hospital level were analysed, and the necessary set of procedures was defined, and the model of management procedures was developed and MD administration, which was initially implemented in five pilot medical institutions. The process continued (2016) through the project "Improving the Management of Medical Devices" (PIM-DM) carried out with the support of the Japanese International Cooperation Agency (JICA), 5 Departments of Biomedical Engineering were established in IMSP: the Institute of Emergency Medicine, the Institute of Mother and Child, The Republican Clinical Hospital, the Oncological Institute and the Municipal Clinical Hospital "Holy Trinity" with the aim of ensuring the optimal conditions for the provision of quality, efficient and safe MD to IMSP, in order to guarantee the quality of the

medical services provided, the complex organisation of daily measures and activities for the current servicing and repairs of MD.

The responsible counterpart for updating and management of the SIMDM is currently the "Agency of Medicines and Medical Devices" [14], a public institution founded in 2013 with the aim to ensure the introduction of quality, efficient and safe MD on the market, of the periodic verification of the medical device put into operation and in use [15]. Periodic verification of medical devices put into operation and in use is carried out by conformity assessment bodies accredited according to Law No. 235/2011 "On accreditation and conformity assessment activities" [16], recognised in the field of MD and independent from manufacturers, users and from the people who ensure the maintenance of MD.

Currently, 41 273 medical devices of 3 893 models are registered in SIMDM. From the point of view of the quantitative endowment with medical devices, the medical institutions are considered sufficiently equipped. But, from a technological point of view, the technological potential of the endowment is physically and morally exceeded, taking into account the rhythms of the development of medical technologies. We note that the degree of moral obsolescence and non-functionality of MD is different in the territory. This obvious factor affects the quality and efficiency of the medical services provided to the population, especially outside the city of Chisinau (the capital of the republic). In this connection, the Government's Action Plan for the years 2021–2022 [17] includes measures to update the legislative framework regarding MD and the modernisation of medical technologies in state medical hospitals and clinics.

Aware of the importance of human resources for adequate management of MD, already in 2005, at the initiative of the Ministry of Health and the Technical University of Moldova, the specialty "Biomedical Engineering" was included in the Nomenclature of Fields and Specialties in higher education and the professions of "Medical Bioengineer" and "Clinical Engineer" were included in the Classifier of occupations from the Republic of Moldova and are provided in the medical staff regulations of the medical entities.

Based on the above, from 2006 at the Technical University of Moldova, within the Department of Microelectronics and Biomedical Engineering [18], undergraduate studies were initiated in the specialty "Biomedical Systems Engineering" (from 2019 – "Biomedical Engineering"). The expansion of the training of specialists in the field of Biomedical Engineering was continued with the initiation of master's studies (2010) within the same Department of Microelectronics and Biomedical Engineering. The study programme follows harmonised European recommendations and is nationally accredited. Up to now, more than 250 medical bioengineers and 80 specialists with master's degrees have been trained, most of whom are employed in the healthcare system.

The nominated TUM Department also provides doctoral studies (since 2017) within the Doctoral School "Computer Science, Electronics and Communications" in the following 3 specialties: Physics and Materials Technology; Nano-Microelectronics and Optoelectronics; Biomedical Equipment and Devices.

The Technical University of Moldova, through the Department of Microelectronics and Biomedical Engineering, together with the State University of Medicine and Pharmacy "N. Testemitanu" was part of the multinational Consortium of 17 participating organisations from 11 countries in the TEMPUS IV project "Tempus Initiative of Education in Biomedical Engineering in the East. Neighbouring area" (BME-ENA). The main goal of the TEMPUS IV project was to advance BME education in the target countries, primarily through the establishment of a new joint master's degree programme in line with European standards and approaches [19]. That will have major positive effects on both the healthcare technology industrial sector, and the healthcare delivery system through appropriate management and safe use of MD. As a result, the BME educational structures in the Republic of Moldova will be reviewed and adapted to new requirements, and the new postgraduate programmes will be generated in accordance with European policy.

In order to support the competitiveness of the training process and the active participation of collaborators and students in the research process within the Department, 3 Centres were organised: the National Center for Biomedical Engineering (2017), the Nanotechnology and Nanosensors Center (2018), and the National Nuclear Security Support Center (2013) which is a member of the International Nuclear Security Education Network (INES).

The National Center for Biomedical Engineering [20] is a subdivision of the Technical University of Moldova with the rights of self-management and self-financing, based on contracts for providing services or organising events with their beneficiaries and in accordance with expenditure estimates and collaborates in its activity with the Ministry of Health, Agency for Medicines and Medical Devices and other central government authorities.

The main purpose and objectives of the Center are to increase the quality of medical services by improving the Management of Medical Devices and to ensure a high level of performance and security of medical devices (MD) in use in medical institutions. The fields of activity of the Center are determined by the activities in organising and providing technical and scientific support services, facilitating the development of human resources, scientific research, and education in the field of Biomedical Engineering as followings:

- The continuous professional training of the managers, the medical and technical personnel from the medical-sanitary institutions in the field of the use of the medical devices as well as for the specialists responsible for the commercialisation and commissioning of the medical devices;
- The elaboration of the mandatory continuous improvement programmes for the specialists working in the field of MD use, as well as for the specialists responsible for the commissioning of MD;
- The provision of technical support, evaluation, and consulting services in the field of MD management;
- Elaboration and implementation of management of medical devices procedures according to national regulations and manufacturers' requirements;
- Elaboration and implementation of MD maintenance procedures;
- Support on services for periodic verification of MD;
- Scientific research in medical engineering;
- Promoting the profession of medical bioengineer in the healthcare system in relation to the requirements and quality standards of the medical act;
- Other types of activity, which do not contravene the legislation in force.

The Centre has extensive experience in MD management. The Centre's staff participated as local experts in two Moldovan-Swiss projects and one Moldovan-Japanese project involving the Japan International Cooperation Agency (JICA).

Based on an Agreement signed with the Ministry of Health of the Republic of Moldova, the Department of Microelectronics and Biomedical Engineering is nominated as the basic institution for the training/retraining of biomedical engineers in the country.

It is important that the training of biomedical engineers is ensured including with the contribution of the State University of Medicine and Pharmacy "N. Testimițanu", which delegates university professors to specific disciplines and ensures that the laboratory works, the annual practice of the students in the respective clinics of the public institutions medical.

The Department of Microelectronics and Biomedical Engineering participates in the exchange of experience with other universities outside the country. There is effective collaboration in the training of staff with the "Grigore T. Popa" University of Medicine and Pharmacy in Iași (Romania). The nominated department organised refresher courses in biomedical engineering (490 hours) for a group of trainees from Turkmenistan, thus contributing to the building of the biomedical engineering infrastructure in this country, annually organising refresher courses for staff from the republic. More than 20 training sessions were organised and conducted for the users of medical devices, and 8 training ses-

sions for the technical staff (medical bioengineers, technicians).

The independent assessment of the situation with DM in the republic was carried out by the People's Advocate, whose report states the following [21]. According to the information gathered from the respondents and during the monitoring visits, it was found that during the years 2014–2017, some of the emergency departments were opened with the support of the Moldovan-Swiss project REPEMOL in the Republic of Moldova, and medical equipment and devices were procured both for equipping emergency reception units as well as resuscitation rooms. These are defibrillators, electrocardiography machines, mobile oxygen, laryngoscopes, etc. To create the units, hospital managers had to identify space, equip the ward with equipment, as well as recruit medical staff. Although the aim of the project was to improve paediatric healthcare, reforms, facilities, and emergency training, carried out within REPEMOL, contributed, including to the improvement of emergency services at the hospital and pre-hospital level for children and adults. In total, 12 emergency reception units and five paediatric intensive care units in the country were reorganised and received modern equipment. In addition, the medical staff was also trained, in accordance with European standards. As part of this project, four emergency reception departments were established: the Bălți Municipal Clinical Hospital, the Cahul District Hospital, the Mother and Child Institute, and the "Valentin Ignatenco" Municipal Hospital.

A technical renovation (2017) at the Institute of Neurology and Neurosurgery was made possible thanks to the investment project "Equipping the Emergency Reception Unit with high-performance medical equipment", financed by the Embassy of the Czech Republic in the Republic of Moldova in the amount of about 16 million USD, and co-financed by the investment project financed from the fund for the development and modernisation of public medical service providers, CNAM in the amount of about 90 thousand USD. The institute was equipped with the most modern furniture and high-performance medical equipment, such as a portable artificial ventilation device with multiple ventilation regimes, cardiorespiratory monitors, emergency and intensive care stretchers, medical aspirators, resuscitation beds, digital pulse oximeters, automatic hematology analysers, etc. Thus, all the necessary conditions were created for the provision of quality emergency medical services to patients with neurological and neurosurgical emergencies.

From the overall analysis of the situation regarding the provision of primary emergency units with the devices necessary to provide emergency medical assistance, the ombudsman noted (important: in the situation of 2018) an insufficiency in the provision of this segment of medical assistance, which somehow compromised the quality the medical

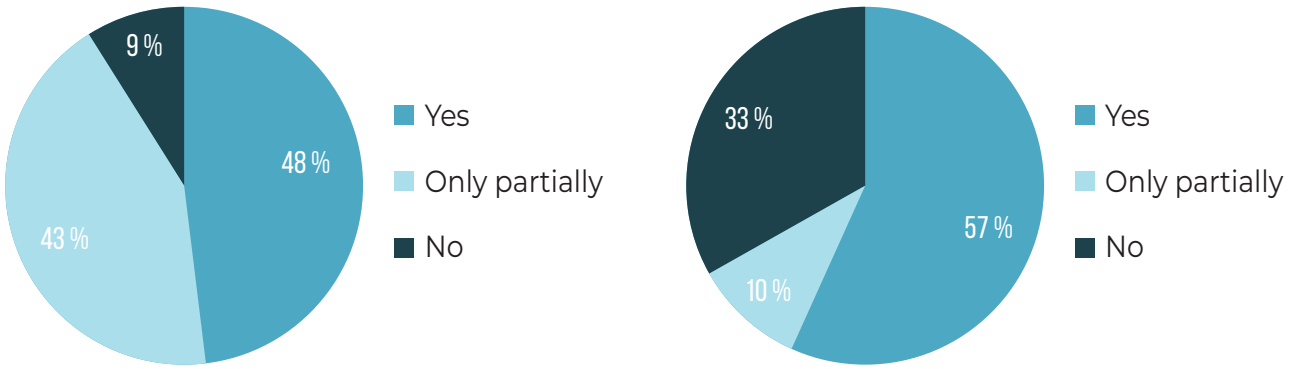

Figure 5. The perception of managers of medical institutions in the need for information/training in the field of equipment management (left); provision of qualified personnel to verify the criticality of medical devices (right) [21]

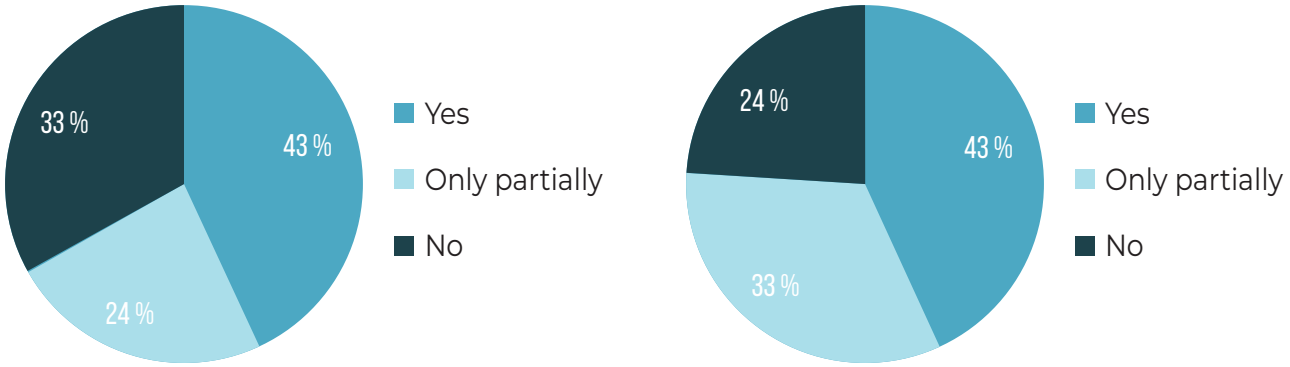

Figure 6. Ensuring the institutions with: adequately trained personnel for the monitoring, evaluation, and periodic verification of MD (left); planned budget for checking and repairing MD (right) [21]

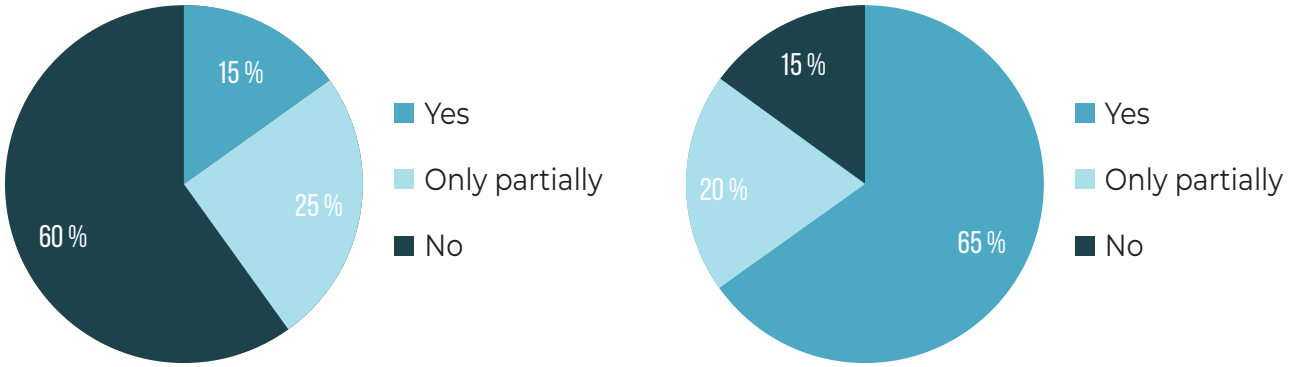

Figure 7. Provision of: MD criticality analysis methods (left); preventive maintenance, correction, and quality control procedures MD (right) [21]

act. But it is necessary to mention that during the pandemic, thanks to the major assistance from the development partners, this insufficiency of the technical endowment of the primary medical emergency assistance units was remedied.

Regarding the situation with personnel dedicated to the management of medical devices, the evaluation of the people's advocate found that the majority of managers (90 %) of medical institutions confirmed the need for information/training regarding the criticality of medical devices. The managers recognise the opportunity of training and perfecting the knowledge of bioengineers, which in their opinion will have a major impact on the healthcare system of the Republic of Moldova and on increasing the quality of the medical act (Figure 5, left) [21]. On the subject of staffing with qualified personnel in assessing the criticality of MD, managers of medical institutions recognised the existence of a substantial shortage of specialists in the field (see Figure 5, right).

It was found that there are cases when the function of monitoring the state of the medical equipment is performed by people without specific specialised training (see Figure 6, left). Referring to the planning of the sufficient budget for the verification and repair of DM, it is found that 76 % of the respondents confirmed the planning, but it depends on the volume of the financial insurance (Figure 6, right) [21].

The results of the survey regarding the institutional DM management procedures show a worrying insufficiency (60 %) of them regarding the methods of analysing the DM criticality (Figure 7, left), and regarding the presence of concrete procedures related to the preventive maintenance, correction, and quality control of the DM 65% of respondents confirmed the presence of such a procedure (Figure 7, right).

Conclusions

The benefits of implementing Medical Device Management are immeasurable. The evaluation of the dynamics of its implementation shows the existing positive impact on the medical system in the Republic of Moldova. We note with satisfaction that the efforts made, with the support of development partners, resulted in the following achievements:

- Increased awareness of decision-making factors regarding the need to implement a state policy in the field of medical device management;
- The legislative-normative framework implemented is in good correspondence with European norms. Efforts are being made to ensure its full potential with existing regulations in the EU;
- Increased share of the national budget for equipping medical institutions with DM, and their maintenance during the life cycle;
- Increased degree of the endowment of medical and sanitary institutions with high-performance MDs and the efficiency of their operation;
- 5 pilot Departments in Biomedical Engineering were established, which confirmed the efficiency of such structures in medical institutions;
- The provision of medical institutions with specialists in biomedical engineering has increased;
- The training of biomedical engineers through bachelor's, master's, and doctorate professional training is under development. Curricula are being developed and implemented for the regular training of medical and engineering personnel in the field of medicine.

Obviously, in the Republic of Moldova, which is a developing country, for objective reasons, there are still gaps in ensuring effective MD management (insufficiency of financial security, limited capacities of the education system to generate specialists in biomedical engineering in a short time).

ACKNOWLEDGMENTS

The present paper was developed within the self-evaluation of the Department of Microelectronics and Biomedical Engineering (Biomedical Engineering profile) carried out according to the provisions of the Project: Setting peer review instruments and goals for medical (Health) education (SPRING), *ERASMUS+* Programme of the European Union 2014–2020, KA2: Cooperation for Innovation and exchange of good practices CBHE – Capacity Building in the field of Higher Education.

Conflicts of interest

The authors declare no conflict of interest.

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