https://doi.org/10.5272/jimab.2023291.4800

Journal of IMAB
ISSN: 1312-773X
https://www.journal-imab-bg.org

Journal of IMAB. 2023 Jan-Mar;29(1)

Original article

APPLICATION AND COMPLIANCE WITH THE MEDICAL STANDARDS IN THE FIELD OF OBSTETRICS, GYNECOLOGY AND RELATED SPECIALTIES IN BULGARIA

Ivan Kostov[1,3], Gergana Ingilizova[2], Sergei Slavov[1,3]
1) University Hospital of Obstetrics and Gynecology "Maichin Dom", Sofia, Bulgaria
2) Vita" Multidisciplinary Hospital for Active Treatment, Sofia, Bulgaria
3) Department of Obstetrics and Gynecology, Medical University, Sofia, Bulgaria.

ABSTRACT

This study has examined and analyzed the public information on inspections performed by the Executive Agency "Medical Supervision" (EAMS) of hospitals in the country - specialized obstetrics and gynaecology hospitals and departments in multidisciplinary hospitals related to Obstetrics and gynaecology (OG), oncogynaecology, neonatology and reproductive medicine for a period of three years (2014 – 2016) in order to establish the presence, frequency and causes of malpractices of the requirements of the relevant medical standard.

Materials and methods: The results of 74 inspections under the medical standard and 29 mixed in 125 medical institutions were analyzed.

Results: In most of the inspections carried out by the Executive Agency "Medical Supervision", no malpractices of compliance with medical standards were found. The established malpractices under the medical standard mainly concerned obstetrics and gynaecology care and the standard of OG – 57,3% and to a much less extent the standards of neonatology and assisted reproduction – 13,6% for each. The largest part of the deviations in medical standards in OG ($p < 0.05$) concerned the accurate maintenance and filling in of the medical documentation – 26.0%, insufficient operational activity – 21.5% and staff qualifications – 18.8%. The main problem in neonatology was the number of medical staff, and in assisted reproduction - 24 hours of continuity of service.

Conclusions: As of date the research outlines the need for future actions to revise the current medical standards in OG, assisted reproduction and neonatology, mainly in terms of how the standard works, whether it needs updating and to what extent it is accepted by the profession.

Keywords: Obstetrics and gynecology, medical standards, malpractices.

INTRODUCTION

The discovery of the degree of preventable medical error has led to an emphasis on improving patient safety [1, 2]. The provision of quality medical care to the population is one of the main objectives in healthcare [3]. The need for quality health services has necessitated the introduction of acceptable standards of quality, efficiency and safety. Standards are normative documents that are developed and determined on the basis of generally accepted rules and principles, approved by consensus of experts or by scientific and medical evidence, described in the specialized literature or on the basis of the obtained results of empirical research. They change in parallel with the development of medical science, often influenced by the economic condition of the health care system. They rely on improving the quality of health care through modern and adequate diagnostic and therapeutic procedures, reducing the use of unnecessary, ineffective or harmful interventions, facilitating the treatment of patients with maximum chances of success, minimum risk and reasonable price [4, 5].

The American surgeon Ernest Codman is a pioneer in creating hospital standards and implementing strategies for evaluating health outcomes. He opened his own hospital, which he called "Hospital of Outcomes", in order to measure the treatment provided and to identify the areas for improvement that he considered important. Codman made public the final results of his hospital treatments by publishing them in a book called "The Study of Hospital Efficiency" [6]. Of the 337 patients treated and discharged between 1911 and 1916, Codman recorded and published 123 errors.

Since then, the health quality movement has undergone a number of changes as a result of the many stakeholders, the variety of unique and modified approaches and constantly evolving goals [7, 8].

Medical standards are essential in the following aspects: 1) Modernization of the regulatory framework of each medical specialty; 2) Structuring and arranging in a standard of the large information array of principles, rules,

norms, requirements, guidelines, recommendations and guidelines for quality medical activity; 3) Communication and cooperation according to the principles and rules applicable in the European Union; 4) In accordance with international practice, medical standards are necessary to protect on a scientifically sound regulatory basis both the rights of medical professionals in the event of unmotivated attacks and accusations and the rights of patients [9].

Currently, in countries with developed and well-functioning health care systems, a number of standards have been created and implemented in medical practice, which regulates the activities related to certain diagnostic or treatment areas. Compliance with them guarantees the provision of quality medical services and serves as a basis for comparison with a specific activity when its quality is subject to assessment [4, 10].

On August 20, 2001, the National Program "Medical Standards in the Republic of Bulgaria (2001-2007)" [11] was approved in Bulgaria, and later in 2008 - the National Program "Medical Standards in the Republic of Bulgaria" (2008 – 2010)" [9]. The purpose of these programs is to provide prerequisites and conditions for the establishment and improvement of medical standards, with a view to improving the quality and efficiency of the health system [12]. Experience shows that they are an effective tool for the management and development of health care based on the quality-guaranteed quality of medical care in Bulgaria. So far, over 55 standards have been adopted in various fields of medicine (medical specialties), recognized by the respective guild as acceptable in the treatment of patients and normatively notified by the state through their adoption by the Ordinances of the Minister of Health.

The first medical standard in Obstetrics and Gynecology in Bulgaria was officially approved by Ordinance No. 32 on December 30, 2008 [13]. The standard is the result of many years of efforts of an author team consisting of: N. Vassilev, I. Kostov, A. Nacheva and S. Kovachev.

From 2008 until today, the medical standard for OG has been revoked and reissued several times. It has undergone a number of corrections, most recently approved by Ordinance No. 9, April 27, 2021, of the Minister of Health [14].

The first medical standard for "Neonatology" in our country was approved by Ordinance No. 34 of 2010 [15], subsequently revoked and corrected as the current standard was approved by Ordinance No. 13 of 23.07.2014, issued by the Minister of Health [16].

In 2007, Ordinance No. 28 on Assisted Reproduction (AR) activities, the first medical standard on Assisted Reproduction in Bulgaria was approved [17]. Over time, it has also undergone many corrections and changes as the ordinance was last revoked by a decision of the Supreme Administrative Court (SAC) on 21. 04. 2020 and currently there is no current standard of AR in the country.

Carrying out inspections or quality control of activities, performed by medical or other professions related to healthcare is known as a medical or clinical audit [18, 19]. This function is performed by a competent authority in the healthcare system - Executive Agency "Medical supervision"- a structure subordinated to the Ministry of Health in Bulgaria. One of the main functions and powers of the EAMS is to carry out inspections for compliance with the approved medical standards in medical institutions and to control the quality of medical care in accordance with these standards.

The aim of the present study was to study and analyze the public information on medical standard inspections carried out in accordance with the medical standards by EAMS in the medical institutions in the country - specialized OG hospitals and departments in multidisciplinary hospitals related to OG, oncogynaecology, neonatology and reproductive medicine for a period of three years (2014 – 2016) and to establish the presence, frequency and causes of malpractices of the requirements of the relevant standard based on the expert assessment of the EAMS.

MATERIALS AND METHODS

According to the types of inspections performed by the EAMS, it can be: 1) on complaints, 2) according to medical standard, 3) mixed. The material of the study covers all available documents from EAMS, according to the medical standard of medical establishments in the country in the clinics/departments of obstetrics and gynaecology, oncogynaecology, neonatology and assisted reproduction (AR) for the period 2014-2016. The results of 74 examinations under medical standard and 29 mixed in 125 medical institutions were analyzed [20]. The sources of information when performing a medical audit are: 1) Documents - contracts, medical files and records, general and special purpose forms, reports on the activities of the providers of medical care, etc.; 2) Physical data media - for direct inspection of activities (schedules, charts, cards, photos, disks); 3) Evidence sources - oral and written statements in response to inquiries, interviews, surveys. The scope of the medical audit under the MS concerns the observance of the standards and the establishment of possible malpractices in the following aspects: 1) Structure of the MI, 2) Medical personnel, according to the level of competence; 3) Qualification; 4) Usability of beds; 5) Operational activity; 6) 24 hours continuity of service; 7) Quality of medical documentation; 8) Apparatus / Equipment.

Statistical data processing was performed with the statistical package SPSS24. MS Excel and MS Word were used for the tabular and graphical presentation of the results.

RESULTS AND DISCUSSION

In the majority of the inspections carried out by the Executive Agency "Medical Supervision" (EAMS) no malpractices were found in terms of compliance with medical standards (Table 1). The established malpractices under the medical standard were mainly in obstetric and gynaecological care in relation to the standard of OG – 57.3% (39.8% of the malpractices are in obstetrics, 17.5% - in gynecology) and to a much less extent in relation to the standards of neonatology and assisted reproduction – 13.6% each (Fig. 1) as the individual sub-specialties differ statis-

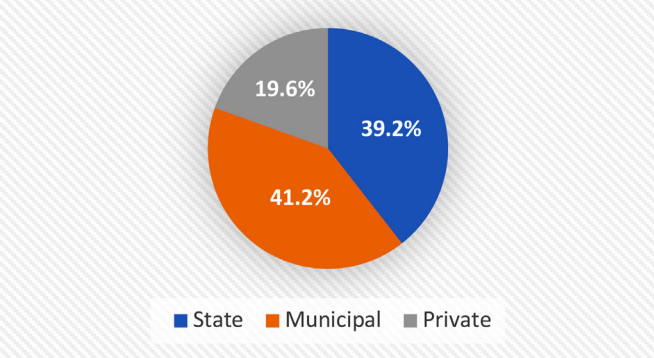
tically significantly ($p < 0.05$) according to the frequency of malpractices. A probable reason could be the different qualification and levels of competence of the medical specialists involved in the implementation of the OG standard in different medical institutions, the different levels of material and technical provision of the medical institutions that offer obstetric and gynaecological care, as well as the wide scope of the standard. Neonatological care and assisted reproduction activities, given their specificity and narrow scope, presuppose qualification in a narrower field of activity, which makes compliance with the relevant medical standards easier to achieve.

Table 1. Type of inspection and distribution of malpractices

			Type of inspection		
			MS	Mixed	Total
Malpractices	Obstetrics	n	29	12	41
		Col%	39.2%	41.4%	39.8%
	Gynaecology	n	12	6	18
		Col%	16.2%	20.7%	17.5%
	Neonatology	n	11	3	14
		Col%	14.9%	10.3%	13.6%
	Assisted reproduction	n	11	3	14
		Col%	14.9%	10.3%	13.6%
	Mixed	n	11	5	16
		Col%	14.9%	17.2%	15.5%
	Total	n	74	29	103
		Col%	100.0%	100.0%	100.0%
P			P<0.05	P>0.05	P<0.05

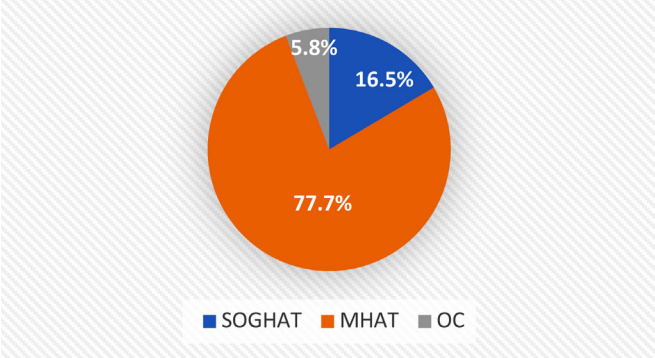
The distribution of medical standard malpractices did not differ statistically significantly in hospitals with different ownership ($p > 0.05$), (Fig. 1).

Fig.1. Distribution of malpractices according to the type of inspection and the ownership of the medical institutions



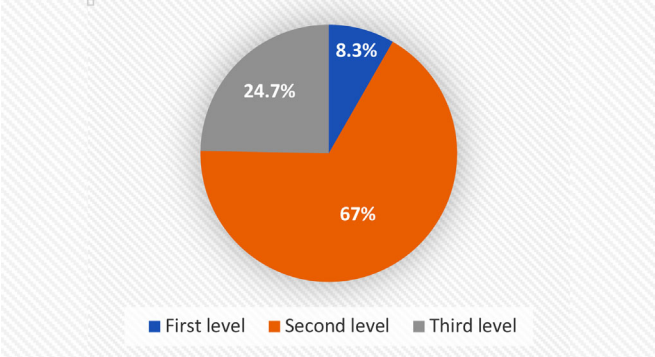
There is a statistically significantly higher percentage of medical standard malpractices in multidisciplinary hospitals for active treatment (MHAT) - 77.7% compared to 16.5% in specialized obstetrics and gynecology hospitals for active treatment (SOGHAT) and 5.8% in outpatient care (OC) ($p < 0.005$) (Fig. 2).

Fig. 2. Distribution of malpractices according to the type of inspection and the type of medical institution



Statistically, a significantly higher frequency of medical standard malpractices was reported in medical institutions of the second level of competence - over two-thirds, compared to medical institutions of the first and third level (Fig. 3).

Fig. 3. Distribution of malpractices according to the type of inspection and the level of competence of the structures of the medical establishments



The data from fig. 2 and fig. 3 logically reflect the concentration of highly qualified staff in specialized obstetric hospitals and units of the first level of competence.

The results regarding the medical standard malpractices in sub-specialties has shown that the largest part of the deviations is in OG ($p < 0.05$) were mainly due to the omissions in maintenance and filling in of the medical documentation - 26.0%, insufficient operational activity - 21.5% and staff qualification - 18.8%. While with regard to the sub-specialties Neonatology and AR, due to their specific nature and the small number of narrow specialists in these fields, the main problems were the number of medical staff (Neonatology) and 24 hours of continuity of service (Table 2).

Table 2. Distribution of malpractices by medical standard and subspecialties

(p < 0,05)	OG			Neonatology			AR			TOTAL		
	number	Row	Col	number	Row	Col	number	Row	Col	number	Row	Col
	n	%		n	%		n	%		n	%	
Structure	26	100.0	11,7	0	0.0	0.0	0	0.0	0.0	26	100	9,5
Sufficient number of medical personnel	23	63,9	10,3	13	36.1	43.3	0	0.0	0.0	36	100	13,2
Qualification	42	79,2	18,8	11	20,8	36,7	0	0.0	0.0	53	100	19,4
Usability of beds	0	0.0	0.0	0	0.0	0.0	0	0.0	0.0	0	0	0.0
Sufficient operational activity	48	100.0	21,5	0	0.0	0.0	0	0.0	0.0	48	100	17,6
24 hours continuity of service	16	61,5	7,2	0	0.0	0.0	10	38,5	50.0	26	100	9,5
Quality of medical documentation	58	78,4	26	6	8,1	20.0	10	13,5	50.0	74	100	27,1
Apparatus	10	100.0	4,5	0	0.0	0.0	0	0.0	0.0	10	100	3,7
Equipment	0	0.0	0.0	0	0.0	0.0	0	0.0	0.0	0	0	0.0
TOTAL	223	81,7	100.0	30	11.0	100.0	20	7,3	100.0	273	100	100.0

The results of the study objectively represented the quality of medical care in the specialty "Obstetrics and Gynecology" and directly related to it "Neonatology" and "Assisted Reproduction". Satisfactory material and technical provision of the OG units was reported, as far as no significant malpractices of the medical standard in this direction have been established. However, there is a serious deficit of qualified medical staff, which is a key prerequisite for providing quality health care. This is a long-standing and deepening negative trend in all medical specialties, but in the specialty of obstetrics and gynaecology, it is especially noticeable. The reasons are the insufficient number of accredited educational institutions for conducting training in the specialty "Midwife", the large outflow from the profession due to the great responsibility and difficult working conditions, including night work, inadequate pay and the serious outflow of qualified personnel abroad due to better conditions of work. As a result of the unattractive working conditions and, accordingly, the profession of a midwife in general, the process of training quality and reliable personnel to fill the serious personnel shortage is very difficult. There is a situation of shortage of qualified personnel in medical institutions- mainly midwives, most of whom are of retirement age and a small number of young specialists with insufficiently good qualifications. There is a serious shortage of doctors specializing in OG, neonatology and anesthesiology, in hospitals in smaller settlements again for the same reasons - low pay, unattractive working conditions. The personnel shortage is the basis of the other deviations according to the medical standard, such as the impossibility to provide 24 hours of specialized care, reduced operational activity in some structures and the impossibility of properly maintaining medical documentation. However, the problem with the gaps in documentation can also be addressed in the inconsistent and out-of-date volume and format of medical records that need to be maintained, excessive bureaucracy and formalism, and especially the lack of uniform or at least separate hospital information systems to allow automatic generation of most of the information and the ability to accurately and comprehensively cover the medical history of each patient with quick access to all diagnostic and treatment measures applied to the patient.

CONCLUSIONS

The analyzed data from performed inspections show that the medical standards in the specialties, subject of the research, are malpractices mainly in the following parts according to their frequency: 1) filling in the medical documentation, 2) number and qualification of the medical specialists, 3) required volume of performed activity (in particular operational activity), 4) structure of the medical institution. These results definitely require a revision of the current medical standards, mainly in terms of the following aspects: how effective the standard is, whether it needs updating, and to what extent it is accepted by professionals.

Currently, five years after the end of the research and as a result of the analyzes, a number of debates and recommendations among expert commissions, professional and patient organizations and control authorities, there is a new standard on "Obstetrics and Gynecology"in Bulgaria, and forthcoming update and approval of a new medical standard on Assisted Reproduction.

Medical standards cover all clinical aspects of the given specialties and should serve as a good basis and guarantor for the provision of high-quality medical care in the field in good faith.

REFERENCES:

1. Penev G, Grigorov E. Analgesic efficacy of preoperative ultrasound transversal abdominal plane block for open hysterectomy. *Biotechnol Biotechnol Equip.* 2022;36(1):346-352. [Crossref]

2.WHO. World Alliance for Patient Safety Forward Programme, 2007.

3. Penev G, Belcheva V, Grigorov E, Salchev P. Medico-social aspects of the anesthesia of normal birth with epidural analgesia. *Bulgarian Journal of Public Health.* 2020; 12(2):21-34. [Internet]

4. Petrova Z, Chamov K, Gladilov Z. [Quality in healthcare. Contemporary dimensions and trends.] [in Bulgarian] Sofia, 2008; Health media group.

5. Ninova M. [Awareness and insight of healthcare professionals into the nature, causes, and organization of health care to limit nosocomial infections.] [in Bulgarian] *KNOWLEDGE - Int J.* 2021 Apr 15;45(4):777-781. [Internet]

6. Codman EA.The classic: A study in hospital efficiency: as demonstrated by the case report of first five years of private hospital. *Clin Orthop Relat Res.* 2013 Jun;471(6):1778-83. [PubMed]

7. Colton D. Quality improvement in health care. Conceptual and historical foundations. *Eval Health Prof.* 2000; 23:7–42.

8. Ninova M. [Knowledge and application of medical devices for the prevention of HAI by health care professionals.] [in Bulgarian] *KNOWLEDGE - Int J.* 2020 Oct 8;42(4):743-749. [Internet]

9. Ministry of Health of the Republic of Bulgaria. National Program "Medical Standards in the Republic of Bulgaria" (2008-2010).

10. Redic EL. Applying focus-PDCA to solve clinical problems. Dimens Crit Care Nurs, 1999; 18(6): 30-34.

11. Ministry of Health of the Republic of Bulgaria. National Program "Medical Standards in the Republic of Bulgaria" (2001-2007).

12. Ministry of Health of the Republic of Bulgaria. Ordinance No. December 19 22, 2014 on the approval of the medical standard "Obstetrics and Gynecology". (Promulgated SG No. 106 of December 23 2014, amended and supplemented, SG No. 37 of May 17 2016).

13. Ministry of Health of the Republic of Bulgaria. Ordinance No. 32 of December 30 2008 on the approval of the medical standard "Obstetrics and Gynecology". (Promulgated SG No. 6 of January 23 2009, amended SG No. 64 of August 17 2010, amended SG No. 95 of December 3 2010, amended SG No. 103 of December 23 2011).

14. Ministry of Health of the Republic of Bulgaria. Ordinance No. April 9 27, 2021 on the approval of the medical standard "Obstetrics and Gynecology". (Promulgated SG No. 41 of May 18 2021).

15. Ministry of Health of the Republic of Bulgaria. Ordinance No. 34 of August 3, 2010 on the approval of the medical standard "Neonatology" (Promulgated, SG No. 64 of August 17 2010).

16. Ministry of Health of the Republic of Bulgaria. Ordinance No. 13of July 23, 2014 on the approval of the medical standard "Neonatology" (Promulgated, SG No. 66 of August 8 2014).

17. Ministry of Health of the Republic of Bulgaria. Ordinance No. June 28 20, 2007 on the approval of the medical standard "Assisted Reproduction" (Promulgated, SG No. 55 of July 6 2007).

18. Petrova Z. Medical audit as an opportunity to manage medical risk. *Scripta Scientifica Medica.* 2011; 43 (7):211-215.

19. National Institute of Clinical Excellence. Principles of Best Practice in Clinical Audit. *Radcliffe Medical Press Ltd.* 2002. 208 pp. [Internet]

20. Kostov I. [Assessment of the Impact of Medical Standard in Obstetrics and Gynecology: Organizational, Clinical and Deontological Aspects]. [Doctoral Thesis] Medical University of Varna. 2017. [in Bulgarian]

Please cite this article as: Kostov I, Ingilizova G, Slavov S. Application and Compliance with the Medical Standards in the Field of Obstetrics, Gynecology and Related Specialties in Bulgaria. *J of IMAB.* 2023 Jan-Mar;29(1):4800-4804. DOI: https://doi.org/10.5272/jimab.2023291.4800

Received: 03/05/2022; Published online: 06/02/2023

Address for correspondence:
Sergei Svetoslavov Slavov, MD, PhD
University Hospital of Obstetrics and Gynecology "Maichin dom", Sofia,
Department of Obstetrics and Gynecology, Medical University- Sofia;
15, Iv. Ev. Geshov Blvd, 1431 Sofia, Bulgaria.
e-mail: sergeislavov66@gmail.com