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GASTROESOPHAGEAL REFLUX DISEASE AFTER LAPAROSCOPIC SLEEVE GASTRECTOMY

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ABSTRACT

Background. GastroEsophageal Reflux Disease (GERD) is a common problem among obese and overweight people, including as a complication of bariatric surgery, Laparoscopic Sleeve Gastrectomy (LSG).

Aim. To conduct a retrospective analysis of the frequency of GERD in patients with morbid obesity after laparoscopic sleeve gastrectomy.

Materials and Methods. In this retrospective study, data from 152 patients who underwent LSG were analyzed. All patients were diagnosed with morbid obesity and were deemed suitable for surgery. The minimum follow-up period was twelve months. All patients were assessed pre-operatively for the severity of GERD using 24-hour pH monitoring, and upper gastrointestinal tract examination via FibroGastroDuodenoScopy (FGDS) to identify signs of reflux disease, esophagitis and Barrett's esophagus and GERD-HRQL (Health-Related Quality of Life) questionnaire.

Results. During the study, out of 152 patients without GERD (DeMeester Index (DMI) was 6.87 ± 3.38), 23 (15.1%) of them within 12 months after LSG developed de novo GERD (DMI 9.12 ± 8.87 , $p=0.04$). In four patients with de novo GERD, esophagitis grade A was detected. The pathomechanism of GERD following LSG was multifactorial, caused by a combination of anatomical, physiological, and physical factors. Contributing factors included the shape of the sleeve, damage to the lower esophageal sphincter, and esophageal motility disorders.

Conclusions. LSG is effective in promoting weight loss, but poses a significant risk of developing GERD. Our study found a 15.1% incidence of GERD after LSG, which is lower than other studies, probably due to the routine use of 24-hour pH monitoring to identify patients with asymptomatic GERD. Anatomical changes due to LSG, in particular resection of the gastric fundus and dissection in the area of the angle of His, increase the temporary relaxation of the lower esophageal sphincter, contributing to the development of GERD.

Keywords: bariatric surgery, morbid obesity, GERD.

INTRODUCTION

Obesity, as defined by the World Health Organization (WHO), is a chronic condition characterized by excessive fat accumulation that may impair health and is identified by a Body Mass Index (BMI) over 30 [1]. Approximately 20% of the

global population is overweight (BMI>25), and 10% suffer from obesity. Unfortunately, in the next 20 years, about 2.16 billion people are expected to be overweight, and 1.12 billion will be obese [2]. Patients with obesity often develop comorbidities, including type 2 diabetes mellitus, arterial hypertension, dyslipidemia, ischemic heart disease, certain types of cancer, and GastroEsophageal Reflux Disease (GERD) [3–7]. GERD is a chronic gastrointestinal disorder characterized by symptoms occurring twice or more per week, worsening the individual's health condition [8–10]. GERD symptoms affect 8% to 33% of the population [11–13], but among those with morbid obesity, this figure can reach up to 63% [14]. GERD symptoms can

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include heartburn, regurgitation, or dysphagia, negatively impacting the individual's quality of life [15; 9]. Furthermore, long-term GERD significantly increases the risk of conditions such as Barrett's esophagus, stenosis, and esophageal cancer [16–18].

There is a strong correlation between GERD and obesity, with obesity being a risk factor for GERD [19–22]. Weight loss, especially through bariatric surgery, significantly improves GERD and overall health [23; 24; 13]. However, the choice of specific bariatric procedures can both improve and worsen GERD, sometimes even causing new cases [25]. This situation leaves GERD a significant issue for many patients following bariatric interventions, especially those who have undergone Laparoscopic Sleeve Gastrectomy (LSG). Similarly, GERD symptoms can appear after Roux-en-Y Gastric Bypass (RYGB) among patients who did not previously have these symptoms [26]. In this review, we will analyze the potential causes of GERD following LSG and examine the occurrence of de novo GERD after LSG.

The aim of study was to conduct a retrospective analysis of the frequency of gastroesophageal reflux disease in patients with morbid obesity after laparoscopic sleeve gastrectomy.

Materials and Methods

In this retrospective study, data from 152 patients who underwent LSG from December 2019 to January 2023 were analyzed. All patients were diagnosed with morbid obesity and deemed suitable for surgery. All procedures were performed in one hospital by a single surgeon experienced in laparoscopic bariatric surgery and GERD surgery. The minimum follow-up period was six months, with four cases lost during the follow-up period. All patients were assessed preoperatively for the severity of GERD using GERD-HRQL (Health-Related Quality of Life) questionnaire, 24-hour pH monitoring, and upper gastrointestinal tract examination via FibroGastroDuodenoScopy (FGDS) to identify signs of reflux disease, esophagitis (classified according to the Los Angeles classification [10] and Barrett's esophagus. Preoperative characteristics of the study population are summarized in *Table*. All patients underwent a preoperative multidisciplinary assessment by a psychologist, dietitian, and anesthesiologist; instrumental assessment included abdominal ultrasound and FGDS. Informed consent for surgery was obtained from each patient preoperatively. The primary outcome measures were weight loss parameters (weight and Body Mass Index (BMI)) and changes in GERD,

the frequency of de novo GERD (defined as [GERD-HRQL score]≥8 or [DeMeester index]>14.72) at 12 months postoperatively.

The LSG procedure was as follows: under general anesthesia and after preparing the surgical field, the patient was placed in the reverse Trendelenburg position with legs apart. Five trocars were inserted. The operating surgeon stood between the patient's legs. A 10-mm trocar was inserted 3 cm above the umbilicus (this trocar was used to introduce the optic with a 30° angle); a second 5 mm or 10 mm trocar was inserted 4 cm below the left costal margin along the left midclavicular line; a third 5-mm trocar was inserted 2 cm below the right costal margin along the right anterior axillary line; a fourth 12-mm trocar was inserted at the umbilicus along the right midclavicular line; and a fifth port was placed along the left anterior axillary line. The first step was to dissect the greater curvature, fundus, and posterior wall of the stomach using Ligasure Maryland (Covidien, USA), starting 5 cm from the pylorus and ending with the dissection of the fundus. The esophagus was intubated using a 38-F or 40-F bougie, which was advanced along the lesser curvature of the stomach. The next surgical step was the sleeve resection of the stomach, which began 5 cm from the pylorus and ended with the resection of most of the greater curvature and fundus of the stomach. The stomach was stapled in stages with triple-row stapler sutures using "Echelon" (Ethicon – Endo Surgery, Johnson & Johnson, USA). Typically, the first two cartridges were green, 60 mm long, with a staple height of 4.1 mm, and the next were blue, with a staple height of 3.5 mm. The gastric cavity was checked for defects by introducing a methylene blue solution.

In statistical analysis, continuous variables with normal distribution were described as [mean±standard deviation]. To compare preoperative and postoperative parameters for each surgery, we used the Chi-square test for categorical variables and the paired Student's t-test for continuous data. An independent sample test was used to compare parameters before and after LSG. A p<0.05 was considered statistically significant. Statistical analysis was performed using Review Manager 5.4 (The Cochrane Collaboration, United Kingdom).

Results

The study involved 152 patients, 74 women and 78 men, who underwent LSG. Patients underwent standard preoperative examination, as well as 24-hour pH monitoring, barium radiography, FGDS, and GERD-HRQL survey. Follow-up was

Table 1. Comparison of patients before and after LSG

	Before LSG (n=152)	After LSG (n=152)	p
Age (mean±SD)	41.12±11.71	-	-
Gender (Female/Male)	74/78	74/78	-
Weight±SD (kg)	125.17±20.11	87.00±16.2	<0.00001
BMI±SD (kg/m ²)	46.14±5.8	27.8±4.5	<0.00001
DeMeester score (mean±SD)	6.87±3.38	9.12±8.87	0.003
GERD-HRQL score	3.65±1.98	4.17±3.45	0.11
GERD, abs. (%)	0 (0.0)	23 (15.1)	0.005
Esophagitis A, abs. (%)	0 (0.0)	4 (2.6)	0.14

conducted twelve months after surgery. Comparative data are presented in *Table*. Exclusion criteria included patients with esophagitis A and above, the presence of a hiatal hernia, [DeMeester index]>14.72, i.e., patients without GERD were selected. Our study data demonstrate the effectiveness of the performed surgery in terms of weight and BMI reduction. De novo GERD developed in 23 (15.1%) patients, (OR=55.5 95% CI 3.33–920.16, p=0.005) with significant confirmation due to pH-metry (DeMeester index). While the GERD-HRQL questionnaire score did not strongly correlate with GERD, the latter is asymptomatic in certain cases. In four patients with de novo GERD, esophagitis grade A was detected.

Discussion

Laparoscopic sleeve gastrectomy has achieved success and widespread popularity worldwide, currently being the most common bariatric surgery in both the USA and Europe [27–29]. LSG, Roux-en-Y Gastric Bypass (RYGB), and One Anastomosis Gastric Bypass can improve or completely resolve GERD. However, improvements in GERD are not observed in all patients after LSG and are often short-term. It should be noted that RYGB impacts GERD symptoms significantly better than LSG, with symptom reduction rates up to 90% [30–32].

Persistent GERD after RYGB is associated with diaphragmatic hernias, lower esophageal sphincter hypotension, and severe esophageal motility disorders. These data encourage the search for new solutions to the problem of morbid obesity and associated GERD, as well as more thorough preoperative patient examinations [33]. LSG is undoubtedly a safe procedure with excellent short-

and long-term results, but the information regarding its impact on pre-existing reflux and the development of de novo reflux is controversial. It is noted that GERD after LSG occurs four times more frequently than after RYGB [34–38].

A meta-analysis of randomized clinical trials studying GERD after LSG showed that GERD occurs in 19% of patients post-LSG while de novo reflux develops in 23% of patients. Additionally, 4% of patients require revisional RYGB due to severe reflux following LSG [39]. GERD remains the primary reason for revision surgeries after LSG [40]. Revisional RYGB after LSG provides remission of GERD symptoms in 94% of cases [41; 42]. GERD significantly reduces the quality of life following bariatric surgeries, associated with decreased physical activity and increased psychological and emotional problems [43; 44]. It should be noted that LSG increases not only the incidence of symptomatic GERD but also the occurrence of hiatal hernias and esophagitis, both in comparison to preoperative conditions and when compared to RYGB, despite the use of proton pump inhibitors [45; 46]. Most patients with endoscopically verified diseases do not exhibit gastrointestinal symptoms, and conversely, digestive system symptoms are not always correlated with endoscopic findings that explain the symptoms [47–49].

The anti-reflux barrier is represented by several anatomical structures at the gastroesophageal junction, with the Lower Esophageal Sphincter (LES) and diaphragmatic crura being the most significant. These structures play a key role in the mechanism of GERD development post-LSG, with anatomical changes in these structures asso-

ciated with the onset of reflux symptoms [50–52]. There are three main types of LES impairment: reduced LES length, motor (hypotonic) disturbances, and Transient LES Relaxations (TLESRs). TLESRs are periods lasting 10–60 seconds, characterized by LES and diaphragmatic crura relaxation, occurring independently of swallowing, which itself relaxes the LES [53–55]. TLESRs are associated with reflux episodes and occur due to a temporary reduction in LES length and subsequent LES pressure decrease, caused by food entering the stomach and gastric distension [56–59]. Compared to normal-weight patients, those with morbid obesity and GERD exhibit a significant increase in TLESRs during the postprandial phase, including episodes with acid reflux [60]. LSG increases the number of TLESR episodes, reduces LES length and pressure, increases the DeMeester index, and prolongs reflux episodes [61–66].

Since the gastric fundus is resected, this leads to a reduction in the vagal reflex during physiological postprandial relaxation, increasing intragastric pressure and potentially causing retrograde stomach propulsion. Additionally, ghrelin reduction, associated with decreased esophageal motility, plays an important role [67–69]. The presence or absence of esophageal motility disorders is also crucial [62]. Furthermore, careful dissection of the angle of His during surgery is important, avoiding excessive blunting and trauma to the LES, and ensuring the sleeve is not too narrow [70].

Sleeve stenosis post-LSG is rare ([0.5–1.0]%), but up to 80% of patients with sleeve stenosis exhibit GERD symptoms, such as nausea and vomiting [71; 72; 68]. Strict patient selection and mandatory preoperative endoscopy are primary steps to prevent and reduce the incidence of postoperative GERD [73]. In general, it is recommended to avoid performing LSG on patients with existing reflux symptoms [74–76].

In our study, we included patients without GERD, including those without asymptomatic GERD, and yet de novo GERD developed in 23

out of 152 (15.1%) patients. Authors report post-operative GERD rates of 4–73%, but the routine use of 24-hour pH monitoring is not mentioned in these studies [77–83; 40]. Routine use of this test allows for the detection of asymptomatic GERD, enabling other bariatric surgeries to be performed on these patients [84; 85]. The study also highlights the refluxogenic nature of the LSG due to the shape of the sleeve, dissection in the area of the angle of His, and resection of the gastric fundus, where ghrelin is produced, which influences esophageal motility, consistent with global data [86–88].

Conclusion

LSG is effective in promoting weight loss, but poses a significant risk of developing GERD. Our study found a 15.1% incidence of GERD after LRH, which is lower than other studies, probably due to the routine use of 24-hour pH monitoring to identify patients with asymptomatic GERD. Anatomical changes due to LSG, in particular resection of the gastric fundus and dissection in the area of the angle of His, increase the temporary relaxation of the lower esophageal sphincter, contributing to the development of GERD. Routine preoperative pH monitoring should be standard for identifying patients with asymptomatic GERD and prescribing them alternative surgeries.

DECLARATIONS:

Disclosure Statement

The authors have no potential conflicts of interest to disclosure, including specific financial interests, relationships, and/or affiliations relevant to the subject matter or materials included.

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CLINICAL STUDY OF CERVICAL CARIES TREATMENT THE EFFECTIVENESS BY ASSESSING COMPOSITE RESTORATIONS CONDITION

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ABSTRACT

Background. Cervical caries is a fairly common teeth pathology and its treatment is carried out in complicated clinical conditions. Therefore, increasing the term of functioning of composite restorations is an urgent task.

Aim. Identification of the effectiveness of a differential approach to dissection of hard dental tissues depending on the depth of enamel microcracks and implementation of professional hygiene in the treatment of cervical caries in the short- and long-term periods.

Materials & Methods. The study involved 50 people (average age [23.28±5.52] years) in whom cervical caries was treated in 72 teeth. All patients were divided into three equal groups based on the number of restorations according to the selected dissection technique and the characteristics of professional hygiene. The dissection technique depended on the depth of the enamel microcracks in Main Group I (MG I), the dissection was carried out within the limits of clinically intact hard dental tissues in Control Group (CG) and Main Group II (MG II). The dental biofilm was removed from the vestibular surface of the teeth by the method of air-abrasive cleaning using the erythritol-based powder in MG I and MG II, the vestibular surface of the tooth was cleaned of dental deposits with a polishing paste without fluoride in CG. The quality of restorations was assessed based on the United States Public Health Service (USPHS) criteria on the day of restoration, 6 and 12 months later. The effectiveness of the prescribed treatment was identified by the dynamic indicators of the dental pulp electroexcitability and the electrical conductivity of the enamel.

Results. There were no partial or completely destroyed restorations in all terms of the observation period. Composite restorations were preserved according to the criteria of "anatomical shape" and "color matching". One year later restoration defects were absent in 61 teeth (84.72%): in MG I – in 22 (91.67%), in CG – in 19 (79.17%), in MG II – in 20 (83.33%). Recurrent caries and symptoms of hypersensitivity were not identified in MG I. A slightly greater effectiveness of the treatment was noted in MG II group in comparison with CG (by 4.16%) that confirms the importance of removing the dental biofilm before restoration by the method of air-abrasive cleaning using erythritol.

Conclusions. The analysis of the state of restorations in the long-term period showed that the dissection technique and the features of professional hygiene affected their quality before restoration. The number of high-quality composite restorations was by 10.42% more on average in MG I than in the other groups. The obtained results make it possible to recommend the proposed method for using in practical dentistry.

Keywords: *electroodontology, electroodontometry, microcracks.*

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INTRODUCTION

Dental caries remains an unsolved contemporary problem despite scientific achievements [1]. The absence of its timely and, most importantly, high-quality treatment can lead to development of complicated forms, loss of teeth and development of systemic diseases. All this reduces the quality of life of the population and turns the problem of

dental caries into a general medical problem [2–4]. The most vulnerable and prone area to pathological changes is the cervical part of the teeth [4]. It can be explained by many factors but primarily by its structural features [2].

Numerous scientists pay attention to the problem of tooth restoration with Cervical Caries (CC) that has not been fully resolved yet [4]. From the point of view of retention and isolation from moisture invasive treatment of CC occurs in complicated clinical conditions [3]. All this can cause aesthetic problems, development of clinical symptoms of dentine hypersensitivity and it can significantly shorten the period of restoration functioning [3]. Thus, according to data [3], the average term of functioning of such restorations is slightly more than 3 years that is significantly less than for restorations of other localizations. This indicator for restoration does not reliably differ from glass ionomer cements and composite materials [5]. In contrast to durability, the clinical effectiveness of composite restorations is higher than with glass ionomers by the criteria of retention, marginal color change and marginal adaptation, but it is similar to recurrent caries, abrasion and development of hypersensitivity [5]. Although it is known that subgingival regions of composites contribute to increased accumulation of dental biofilm and they cause gingival irritation [6]. But taking into account patients' aesthetic requirements light-curing materials are more often used for direct restorations of CC [3; 6]. In addition, these filling materials also attract doctors owing to the possibility of minimal dissection of hard dental tissues without taking into account biomechanical and functional requirements [7]. Short-term preservation of restorations leads to repeated surgical interventions, loss of intact tissues and the dentist's additional time [8]. Therefore, the problem of improving the effectiveness of treating CC remains relevant having general medical and social importance for preserving the health and quality of life of the population, and it requires further research [1].

Today there are no objective criteria, the compliance of which would allow us to consistently achieve success in the invasive treatment of CC. In our opinion, which is also shared by Peumans M. et al. [9], such a criterion can be the state of hard dental tissues and the method of their preparation for restoration. The results of modern research demonstrate a high prevalence of microcracks in the enamel of permanent teeth which reaches almost one hundred percent on the vestibular surface [10]. The development of cracks is associated

with many reasons, one of which is the structural features of the cervical region of the teeth [10; 11]. The danger of their presence is in the fact that they can be the ways of penetration of microorganisms that can cause the development of other pathologies including the carious process and hypersensitivity of the dentin [10]. Thus, underestimation of the factor of the presence and depth of enamel cracks can lead to a violation of the marginal fit of restoration, its partial or complete destruction and, therefore, a decrease in the quality of treatment [9]. The authors offered a method of treating CC which involves a differential approach to advanced dissection of hard tissues depending on the depth of enamel microcracks on the vestibular surface of the teeth [9].

Aim. Identification of the effectiveness of the proposed differential approach to dissection of hard dental tissues depending on the depth of enamel microcracks on the vestibular surface and implementation of professional hygiene in treating CC in young patients in the near and long-term periods.

Materials & Methods

The study involved 50 patients (30 women, 20 men) treated at the Department of Dentistry No.2 of Donetsk National Medical University. The selection criteria were young age according to the WHO classification (2017), absence of bad habits, pregnancy and lactation period, neoplasms, peculiarities of the household and work history, diagnosed CC, good oral hygiene condition; the obtained written consent to participate in the study. The number of CCs in one patient was from one to four. 72 teeth of frontal and lateral groups with viable pulp were treated under the same clinical conditions, rubber dam and retraction thread were used for isolation.

The examined patients were divided into three equal groups based on the number of restorations according to the principle of randomness depending on the technique of dissection of hard dental tissues and the characteristics of professional hygiene before restoration: Main Group I (MG I) (16 patients), Control Group (CG) (15 patients) and Main Group II (MG II) (19 patients). The formed groups did not differ in age (average age [23.28±5.52] years), sex, level of oral hygiene (according to the Oral Hygiene Index-Simplified (OHIS) (Green-Vermillion, 1964) [0.56±0.40] points), Decayed, Missing and Filled Teeth (DMFT) indices (10.24±4.66), Papillary-Marginal-Alveolar index (PMA) (Parma, 1960) [20.18±17.81]%, pH of oral fluid [6.65±0.51], ($p>0.05$) [12].

According to the proposed method a differential approach to dissection technique of hard dental tissues was used depending on the depth of enamel microcracks in the MG I [9]. If microcracks were diagnosed on the vestibular surface of the tooth with the naked eye under normal lighting, prophylactic dissection of hard tissues, which reached 1.5–2.0 mm, was carried out on the periodontal wall of the carious defect, and on the occlusal wall – on 0.5–1.0 mm. If there were enamel microcracks on the vestibular surface of the tooth, which were identified with the help of additional illumination or magnification or with the use of coloring substances, preventive dissection of hard tissues was carried out on the occlusal wall of the carious defect by 1.5–2.0 mm, and on the periodontal wall – by 0.5–1.0 mm [9]. Dissection was made within clinically intact hard tissues of the teeth in CG and MG II. The gingival wall of CC was located above or at the level of the gingival margin in all restorations.

Preparation of the teeth for restoration included professional hygiene that depended on the observation group. The dental biofilm was removed from the vestibular surface of the teeth by the method of air-abrasive cleaning with AIR-FLOW device using the erythritol-based powder Air-Flow®Plus (EMS, Switzerland) in MG I and MG II [10]. The vestibular surface of the tooth was thoroughly cleaned of dental deposits with the help of polishing paste without fluorine Cleanic (Kerr, USA) in CG. The teeth were washed with water and dried after professional hygiene. Medical treatment of the formed cavities was carried out with a 2% aqueous solution of chlorhexidine bigluconate. The adhesive system of total etching of the 5th generation (Adper™ Single Bond 2 [3M ESPE]) and the light-hardening microhybrid composite material Filtek Z-250 (3M ESPE) were used in accordance with the manufacturer's recommendations. Microhybrid composites are currently effective materials due to their chemical and physical characteristics [13]. The method of "impulse" polymerization was chosen that has certain advantages. Final grinding and polishing was performed using Sof-lex discs (3M ESPE, St Paul, Mn, USA), the effectiveness of which was experimentally proven by modern investigations [14].

The assessment of the quality of composite restorations was carried out at least 30 minutes later after their final processing and in the long-term periods (6 and 12 months later). The clinical examinations included interviews, history taking, visual and instrumental examination of restorations

according to the modified United States Public Health Service (USPHS) quality criteria: anatomical shape, marginal adaptation, surface roughness, marginal staining, color matching, discomfort/sensitivity, presence of recurrent caries. The effectiveness of the prescribed treatment was identified by the dynamics of indicators of the electroexcitability of the dental pulp (the method of ElectroODontometry (EOD) using the electroodontometer EOT-01 [OSP 1.1 MODIS, Averson]) and the electrical conductivity of the enamel at the tooth-restoration boundary (the method of electrometry (EOM) using the "DentEst" device ["Geosoft Dent"]) and the greatest value [10] was taken into account. The marginal staining of restorations was detected using Schiller-Pysarev solution.

Statistical analysis was performed using Microsoft Office Excel spreadsheet editor and Wolfram Alpha online calculator. The correspondence of quantitative indicators to a normal distribution was assessed with the help of Shapiro-Wilk test. After confirming the normality of the distribution with the use of Excel ver. 2312 (Microsoft, USA), Wolfram Alpha was applied for further analysis in order to identify the reliability of differences between the groups according to the studied indicators. When comparing average indicators in normally distributed populations, Student's t-test was calculated. Differences at $p \leq 0.05$ were considered statistically significant.

Results

The observation groups did not differ reliably before treatment and after restoration of CC according to the objective criteria, $p > 0.05$ (Tables 1, 2). The best results were obtained immediately after treatment. Restorations met aesthetic quality criteria. The complaints about the sensitivity of the teeth due to the irritant effects were absent that was confirmed by EOM and EOD indicators.

A slight reliable decrease in the average EOD indicators and an increase in EOM were determined in all groups 6 months later. Restoration defects were also diagnosed according to clinical criteria. The differences between EOM indicators were greater (by 3.6%, $p = 0.0015$) in CG 6 months later after treatment and on the day of restoration than in MG I and MG II (by 2.3%, $p = 0.012$ and by 2.8%, $p = 0.0058$, respectively). The difference between the average indicators of CC in MG I and CG was significant ($p = 0.05$). There were no differences between MG II and MG I and CG ($p = 0.19$ and $p = 0.18$, respectively). The complaints were absent in MG I, but during the electrometric

Table 1. Electrometric assessment of the quality of marginal fit of restorations at different periods of observation (indicator of marginal permeability, μA) ($M\pm m$)

Terms of the observation period	Observation groups		
	Main I	Control	Main II
On the day of restoration	0.087 \pm 0.074	0.117 \pm 0.076	0.108 \pm 0.078
6 months later	0.283 \pm 0.393*	0.546 \pm 0.634*	0.412 \pm 0.538*
12 months later	0.571 \pm 0.509**	1.045 \pm 1.465*	0.887 \pm 1.081**

Notes: * – significant differences in comparison with OEM indicators on the day of restoration ($p\leq 0.05$);
 ** – significant differences compared to OEM indicators 6 months later after restoration ($p\leq 0.05$).

Table 2. EOD indicators of teeth at different periods of observation (μA) ($M\pm m$)

Terms of the observation period	Observation groups		
	Main I	Control	Main II
On the day of restoration	6.75 \pm 0.53	6.54 \pm 0.51	6.67 \pm 0.48
6 months later	6.45 \pm 0.51*	6.08 \pm 0.50*	6.29 \pm 0.48*
12 months later	6.08 \pm 0.28**	5.75 \pm 0.44**	5.91 \pm 0.28**

Notes: * – significant differences in comparison with EOD indicators on the day of restoration ($p\leq 0.05$);
 ** – significant differences compared to EOD indicators 6 months later after restoration ($p\leq 0.05$).

assessment of restorations in one tooth (4.2%), the marginal fit had the signs of an initial integrity violation (EOM 2.1 μA). In CG there was an increase of EOM up to 2.1–2.2 μA in three teeth (12.5%), in MG II – in two teeth (8.3%) that corresponded to a violation of the marginal fit of restorations.

EOD indicators of the teeth in CG were significantly lower than those of the other groups. The difference between EOD indicators of the teeth was greater (by 7.0%, $p=0.0015$ and by 5.7%, $p=0.008$, respectively) in CG and MG II than in MG I (by 4.4%, $p=0.029$) 6 months later after treatment and on the day of restoration. Differences in EOD indicators were significant between CG and MG I and MG II ($p=0.0048$ and $p=0.02$, respectively). There was no difference between CG and MG II ($p=0.179$). The decrease in EOD indicators up to 5 μA in two patients of CG (8.3%) and one patient of MG II (4.2%) corresponded to the appearance of complaints about tooth sensitivity to temperature stimuli.

12 months after treatment, there was a further increase in EOM indicators that corresponded to the deterioration of the marginal fit of restorations both in comparison with the day of restoration and with the previous observation period. The differences were significant in comparison with the day of restoration ($p\leq 0.002$) in all groups. The differ-

ence between the mean EOM indicators was significantly greater (7.9% and 7.2%, respectively) in CG and MG II than in MG I (5.6%) 12 months later after treatment and on the day of restoration. Comparing EOM indicators with the previous observation period (6 months) one year later after treatment, significant differences were identified in MG I and MG II ($p=0.017$ and $p=0.031$, respectively). There was no difference in the average indicators of CC in CG ($p=0.06$).

One year later a further slight decrease in EOD indicators was determined both in comparison with the day of restoration ($p<0.001$) and with the observation period of 6 months ($p\leq 0.009$). At the same time, significant differences were observed in EOD indicators between MG I and CG and MG II ($p=0.003$ and $p=0.043$, respectively). There was no difference between CG and MG II ($p=0.179$). Therefore, during all observation periods EOD indicators differed significantly in the groups ($p\leq 0.03$).

Based on both purely clinical and aesthetic criteria the deficiencies were identified among restoration defects. However, there were more often diagnosed defects that had their combination. The patients of MG I had no complaints, but during the clinical examination a slight roughness of the surface of restoration was determined in one restoration (4.2%). This restoration corresponded to an in-

crease in EOM indicators up to 2.1 μA . Another restoration (4.2%) had a poorly expressed marginal staining in combination with a violation of the marginal fit (electrical conductivity at the tooth-restoration boundary was equal to 2.3 μA and increased by 0.2 μA compared to the previous observation period) that corresponded to the initial degradation of the surface restoration. The patients of CG had a violation of marginal adhesion (EOM=[2.2–5.4] μA) in four restorations (16.7%) half of which were associated with minor marginal staining and the other half – with sensitivity to temperature stimuli. In combination with the symptoms of sensitivity and increased marginal permeability of restorations the signs of recurrent caries were diagnosed in two teeth (8.3%). In addition, during the clinical examination a slight roughness of the surface of the material was determined in one restoration (4.2%). Three restorations (12.5%) with impaired marginal adaptation were diagnosed in MG II. In one clinical case the increase in marginal permeability was associated with slight marginal staining, in another case EOM increased from 2.1 μA to 5.3 μA compared to the previous observation period that corresponded to the development of recurrent caries. In addition, one restoration (4.2%) had slight surface roughness and two restorations (8.3%) had the symptoms of hypersensitivity in MG II. Certain restorations with surface roughness did not require any replacement, the aesthetic defect was eliminated by polishing the changed areas.

Discussion

Thus, a year later, 61 teeth with CC (84.72%) had high-quality composite restorations: in MG I – in 22 teeth (91.67%), in CG – in 19 teeth (79.17%), in MG II – in 20 teeth (83.33%). The preservation of composite restorations was identified according to the criteria of "anatomical shape" and "color matching" which depended to a greater extent on the properties of the filling material and the level of its polymerization. There were no restorations that were partially or completely destroyed. There were no objective signs of the development of recurrent caries and the appearance of the symptoms of hypersensitivity in MG I. During the year there was an increase in the amount of current that was conducted at the tooth-restoration boundary. At the same time, there was a smaller increase in current in MG I compared to both the previous observation period (6 months) and the day of restoration ($p < 0.001$). In our opinion the better results obtained in MG I indicate that the presence and depth of enamel microcracks on the

vestibular surface of the teeth must be taken into account when treating CC. The use of a differential approach to advanced dissection (removal of the areas of changed enamel with microcracks, overhanging edges) made it possible to increase the efficiency of restorations, as the filling material was fixed to unchanged hard tissues [9]. A greater number of restoration defects in CG of the study and slightly better results in MG II (by 4.16%) confirm the opinion about the importance of removing dental biofilm before restoration.

Monitoring dental caries treatment is an effective way to assess its quality. However, the interval of individual examinations should be determined carefully since their greater frequency can lead to an increase in the frequency of interventions [15]. The complaints about hypersensitivity were accompanied by a decrease in EOD and they were identified in the patients with significantly worse indicators of oral hygiene index ($t = 0.0007$). Cervical restorations can contribute to the increased accumulation of dental plaque that potentially leads to the development and progression of recurrent caries and periodontal diseases [13]. A violation of the marginal fit of restorations was determined in the patients not only with higher indicators of the hygiene index, but also of PMA index ($t = 0.002$ and $t < 0.001$, respectively). Probably, it can be explained by insufficiently effective individual oral hygiene measures in these patients. Besides, the stresses that occur in the hard tissues of the cervical region of the teeth after restoration often cause the formation of cracks in the enamel and dentin, a violation of the tightness and marginal fit of fillings [4; 5]. Cervical edges showed more microleakage than occlusal edges [16]. Violations of the marginal fit of the material, especially on the periodontal wall, quite often lead to the development of marginal staining at the boundary of the material with enamel [3]. The patients with a diagnosed violation of marginal adaptation of restorations did not always have complaints. Other researchers also did not observe any relationship between discomfort and the value of marginal permeability. One of the disadvantages of an aesthetic nature was the development of marginal staining at the tooth-restoration boundary for the prevention of which it was suggested to remove the causative factor namely plaque accumulation and high-quality polishing of restorations [17]. The surface roughness identified in some restorations probably depended on the level of their polymerization, polishing, as well as the state of oral hygiene. Therefore, the effectiveness of treat-

ment depends not only on the features of the cavity dissection or on the material that was used for restoration, but also on the patient's characteristics [13].

Conclusions

The analysis of the state of tooth composite restorations with CC according to the USPHS criteria showed that a differential approach to the technique of dissection of hard dental tissues depending on the depth of enamel microcracks affects their quality that was confirmed by the dynamics of clinical, biophysical and statistical indicators. Its application and removal of dental biofilm by the method of air-abrasive cleaning with AIR-FLOW device using an erythritol-based powder contributed to an increase in the effectiveness of treating CC in MG I, on average, by 10.42% one year later compared to other observation groups where dissection was carried out according

to generally accepted requirements. The obtained results make it possible to recommend the proposed method of treatment for using in practical dentistry.

DECLARATIONS:

Disclosure Statement

The authors have no potential conflicts of interest to disclosure, including specific financial interests, relationships, and/or affiliations relevant to the subject matter or materials included.

Data Transparency

The data can be requested from the authors.

Statement of Ethics

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IDENTIFICATION OF RISK FACTORS INFLUENCING PREGNANCY COMPLICATIONS DEVELOPMENT

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ABSTRACT

Background. According to the WHO, about 830 women die every day worldwide from preventable causes related to pregnancy and childbirth. In the recent years, Kharkiv region remains one of the problematic regions of adverse pregnancy outcomes according to the integrated assessment of the Ministry of Health of Ukraine. Against the backdrop of an unfavorable demographic situation, the problem of researching various aspects of the pregnancy period is becoming more and more urgent. Most of the complications that occur during pregnancy are considered from the side of general medical approaches, including hormonal disorders, infectious complications, immunological disorders, etc.

The aim of the work was to study and assess the influence of risk factors on pregnancy complications.

Materials and Methods. For the study, the pregnant women were distributed into two groups: the Main Group (MG) included 299 pregnant women who had complications during pregnancy, and the Control Group (CG) – 199 pregnant women with a normal pregnancy. The median (minimum; maximum) age was in MG was 32 (21; 44) years, in CG – 31 (24; 45) years ($p>0.05$). The median values of the pregnancy period during the survey were 28 weeks for the MG and 26 weeks for the CG ($p>0.05$).

Results and Conclusions. It was determined that biological, socio-economic and socio-psychological lifestyle factors have the greatest influence. The presence of diseases of the cardiovascular system (including hypertension) and diseases of the genitourinary system in a pregnant woman increased the risk of complications during pregnancy by 31.4 times in MG; and by 23.3 times – in CG. The presence of stress in everyday life and, as a result, the deterioration of the psychological state of the pregnant woman increased the chances of pathology of the course by 42.6 and 40.7 times, respectively. Low financial status of the family increased the risk by 16.5 times.

Keywords: *pathology of pregnancy, preventable deaths of pregnant women, stress.*

INTRODUCTION

Against a background of the ongoing large-scale armed aggression of the Russian Federation against Ukraine, the COVID-19 pandemic, the negative demographic situation in Ukraine is getting worse. The issue of preserving and strengthening reproductive health as an integral component of the population's health is becoming extremely strategic for ensuring the sustainable development of society in general. The health status

of pregnant women remains unsatisfactory. After all, the health of the pregnant women affects the outcome of pregnancy and childbirth, determines the viability of offspring at all stages of ontogenesis, the health of newborns and future generations [1–3].

At present, despite the positive trend, almost every sixth pregnant woman is still diagnosed with anemia, which largely depends on the quality and adequate nutrition, which is caused primarily by the socio-economic status of the family and is a marker of the socio-economic well-being of the country.

The complex environmental situation causes a high frequency with a negative trend of thyroid disease in pregnant women 9.98 per 100 pregnant women in 2018 and 10.6 in 2022. An extremely

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serious problem in Ukraine is the increase in the incidence of diabetes among pregnant women – from 0.62 per 100 pregnant women in 2018 to 1.1 in 2022. There was also a trend towards an increase in the frequency of diseases of the genitourinary system, which is interpreted mainly as a consequence of low reproductive culture and irresponsible sexual behavior – from 13.97 to 14.1 per 100 pregnant women in 2021 and 2022, respectively. Diseases of the genitourinary system are one of the reasons for the development of gestosis in pregnant women, premature discharge of amniotic fluid, impaired reproductive functions of the female body, and increase the risk of perinatal mortality and disability in children. With a positive trend, the frequency of diseases of the circulatory system remains quite high – 7.57 and 6.54 per 100 pregnant women, respectively [4].

Pathology of the course of pregnancy is one of the urgent problems of modern obstetrics and a medical and social problem.

Pregnancy complications development is influenced by many factors, extragenital pathology is one of them. The value of extragenital pathology does not decrease. The steady increase in its frequency is caused by the deterioration of the population's health and the increase in the specific weight of women over 35 years old among pregnant women. The presence of extragenital pathology is a risk factor for up to 20% of maternal and up to 40% of perinatal mortality [5–10].

Current evidence suggests a close relationship between social determinants and pregnancy outcomes. According to the WHO, social determinants are defined as mediated factors between living conditions and access to medical care. The study of determinants that have a reliable influence on the occurrence of pathological pregnancy has an important medical and social significance for the development of preventive measures and improving the quality of medical care for pregnant women at the regional level [11; 12].

The aim of the work was to study and assess the influence of risk factors for pregnancy complications.

Materials and Methods

The study involved 598 pregnant women aged 21–45 who were under hospital treatment or under the supervision of City Maternity Hospital No.1 of Kharkiv City Council and City Clinical Maternity Hospital No.7 of Kharkiv City Council. Two groups were formed: the Main Group (MG), which included 299 pregnant women who had complications during pregnancy, and the Control

Group (CG), which included 199 pregnant women with a normal course. The observation groups were valid for comparison, since the median (minimum; maximum) age of the women of the MG was 32 (21; 44) years, women of the CG – 31 (24; 45) years ($p>0.05$). The study and analysis were carried out by copying the data of accounting medical documentation (individual card of a pregnant woman and a woman giving birth (form 111/0); medical card of an inpatient (form 003/0).

The author's questionnaire was used for the survey ("Questionnaire for the study of risk factors for the occurrence of pregnancy pathology"). The questionnaire contained general questions about age, gender, place of residence, etc. The main domains of the questionnaire regarding risk factors for the development of a pathological course of pregnancy were: level of education, temperament, work activity, psychological state, financial capacity, bad habits, data on the course of pregnancy, somatic diseases, peculiarities of nutrition, rest, activity mode. All pregnant women participated in the study signed the informed consent. When conducting a medical-statistical analysis of the distribution of qualitative and quantitative signs, the presence of reliable differences from the normal nature of the distribution was established. Non-parametric statistical analysis for two independent sample populations Mann-Whitney test was used to compare median values. Fisher's test was used to compare proportions.

To determine risk factors for the occurrence of a pathological course of pregnancy, logistic regression analysis was used with the calculation of the Odds Ratio (OR) of the occurrence of the event according to the z-criterion, and their 95% Confidence Interval (CI) was determined using the program package "MedCalc Software" version 22.023 (MedCalc Software Ltd, Belgium). The difference in the parameters of the table was considered statistically significant at $p<0.05$ and if the CI did not contain "1".

The median values of the pregnancy period during the survey were 28 weeks for the main group and 26 weeks for the control group ($p>0.05$).

Results and Discussion

As a result of the research, the factors that have a significant impact on the occurrence of complications during pregnancy were identified. They were distributed into four groups: medical and biological (these include the presence of extragenital pathology and obstetric and gynecological his-

tory), lifestyle factors: social, socio-economic and socio-psychological.

During the analysis of the presence of extra-genital pathology in pregnant women who participated in the study, it was found that the following had a significant impact on the course of pregnancy: cardiovascular diseases (OR=31.4 95% CI 4.2–230.1, p=0.0007); kidney disease (OR=23.3, 95% CI 3.1–171.1, p=0.0020); thyroid disease (OR=14.3, 95% CI 3.4–60.1, p=0.0003); somatoform autonomic dysfunction (OR=4.0, 95% CI 2.3–6.8, p=0.0001) (Table 1).

In the process of studying the factors of obstetric and gynecological history, it was established that the physiological course of pregnancy was characteristic of women with the first pregnancy, that is, complicated pregnancy is characteristic of the second and subsequent pregnancies (p<0.05).

Previous cesarean deliveries (OR=3.2) and a history of medical abortions (OR=1.8) complicate the course of pregnancy. The presence of menstrual cycle disorders in the gynecological history increases the risk of abnormal pregnancy by 8.2 times (OR=8.2, 95% CI 5.4–12.4, p=0.0001) (Table 2).

The analysis of lifestyle risk factors, which can potentially influence the occurrence of pathology during pregnancy in women, allowed us to identify several of them. Pregnant women of the MG drank coffee (more than one cup per day) 10.4 times more often during pregnancy compared to pregnant women with a physiological course (OR=10.4, 95% CI 1.3–79.8, p=0.0236). The presence of harmful habits in the child's father 10.5 times increases the risk of disorders during pregnancy. Non-compliance with the diet, especially

Table 1. Extragenital pathology in examined pregnant women

Disease	Output data (pregnant women)				OR	95% CI	p
	a	b	c	d			
Diseases of the cardiovascular system (including arterial hypertension)	41	258	1	198	31.4	4.2–230.1	0.0007
Diseases of the respiratory tract	15	284	6	193	1.7	0.6–4.4	0.2813
Somatoform autonomic dysfunction	89	210	19	180	4.0	23.0–6.8	0.0001
Diabetes	7	292	1	198	4.7	0.5–38.8	0.1467
Disease of the thyroid gland	38	261	2	197	14.3	3.4–60.1	0.0003
Kidney disease	35	264	1	198	23.3	3.1–171.1	0.0020
Infections of the urinary system	17	282	8	191	1.4	0.6–3.4	0.4067
Others	16	238	1	198	11.1	1.4–85.1	0.0001

Notes: a – women with a complicated pregnancy and the presence of a symptom; b – women with complicated pregnancy and absence of symptoms; c – women with physiological pregnancy with the presence of a sign; d – women with physiological pregnancy and absence of a sign.

Table 2. Risk factors obstetric and gynecological history of complicated pregnancy

Obstetric history	Output data (pregnant women)				OR	95% CI	p
	a	b	c	d			
First pregnancy	90	209	110	89	0.3	0.2–0.5	0.0001
Cesarean section	62	237	15	184	3.2	1.7–5.8	0.0001
Premature birth	13	286	4	195	2.2	0.7–6.9	0.1696
Miscarriages	27	272	9	190	2.0	0.9–4.5	0.0620
Medical abortions	76	223	31	168	1.8	1.1–2.9	0.0094
Missed abortion	27	282	10	189	1.8	0.8–3.8	0.1205
Violation of the menstrual cycle	213	86	46	153	8.2	5.4–12.4	0.0001

Notes: a – women with a complicated pregnancy and the presence of a symptom; b – women with complicated pregnancy and absence of symptoms; c – women with physiological pregnancy with the presence of a sign; d – women with physiological pregnancy and absence of a sign.

the use of fast food and insufficient amount of fruit, has an effect on the course of pregnancy (OR=6.2, 95% CI 4.1–9.2, p=0.0001) and (OR=6.0, 95% CI 3.6–9.9, p=0.0001) respectively (Table 3).

During the investigation, a reliable influence of stress in everyday life and, as a result, the occurrence of a depressed emotional state in a pregnant woman on the occurrence of pregnancy complications was revealed in 42.6 and 40.7, respectively (OR=42.6, 95% CI 5.8–311.0, p=0.0002); (OR=40.7, 95% CI 5.5–297.1, p=0.0003). The dependence of the course of pregnancy on marital status was revealed, an unmarried woman is 4.4 times more likely to have a complicated course of pregnancy (OR=4.4, 95% CI 2.7–7.1, p=0.0001). A low level of income 16.5 times increased the

risk of pregnancy complications (OR=16.5, 95% CI 3.9–69.1, p=0.0001) (Table 4).

Other authors' studies have also assigned an important role to extragenital pathology in the occurrence of pregnancy complications. The key place among which is occupied by cardiovascular diseases, endocrine disorders, systemic damage of connective tissue, etc. Scientists distinguish various factors that determine complications of pregnancy: environmental, psychological, social, etc. Among the peculiarities of the psychological state of the pregnant woman, which affect the development of the child, the following are noted: stress, depressive states, psychopathological features, their occurrence and exacerbation in different periods of pregnancy. Thus, our results are consistent with those of other authors.

Table 3. Social risk factors (lifestyle)

Risk factor	Output data (pregnant women)				OR	95% CI	p
	a	b	c	d			
Smoking before pregnancy	27	272	6	193	3.1	1.2–7.8	0.0118
Harmful habits of the child's father	173	126	24	176	10.5	6.4–17.1	0.0001
Non-compliance with the diet	178	121	67	122	2.8	1.9–4.2	0.0001
Regular consumption of fast food	202	97	50	149	6.2	4.1–9.2	0.0001
Infrequent fruit consumption	128	171	22	177	6.0	3.6–9.9	0.0001
Coffee consumption	15	284	1	198	10.4	1.3–79.8	0.0236
Low physical activity	256	36	145	54	2.2	1.4–3.4	0.0005

Notes: a – women with a complicated pregnancy and the presence of a symptom; b – women with complicated pregnancy and absence of symptoms; c – women with physiological pregnancy with the presence of a sign; d – women with physiological pregnancy and absence of a sign.

Table 4. Socio-economic and socio-psychological risk factors

Risk factor	Output data (pregnant women)				OR	95% CI	p
	a	b	c	d			
Stress in everyday life	53	246	1	198	42.6	5.8–311.0	0.0002
Choleric personality temperament type	132	167	78	121	1.2	0.8–1.7	0.2734
Holding a management position at work	38	261	11	188	2.4	1.2–4.9	0.0103
Lack of higher education	59	240	26	173	1.6	0.9–2.6	0.0542
Low level of material condition	43	256	2	197	16.5	3.9–69.1	0.0001
Marital status (single)	123	176	27	172	4.4	2.7–7.1	0.0001
Psychological (depressive) state during pregnancy	51	248	1	198	40.7	5.5–297.1	0.0003

Notes: a – women with a complicated pregnancy and the presence of a symptom; b – women with complicated pregnancy and absence of symptoms; c – women with physiological pregnancy with the presence of a sign; d – women with physiological pregnancy and absence of a sign.

Conclusions

1. Our findings allowed identification of risk factors, which, according to the calculation, have the greatest impact on the occurrence of pregnancy complications; they were divided into biological and lifestyle factors. Lifestyle factors are divided into three categories: social, socio-economic, and socio-psychological.

2. Our findings suggest that the most influential biological factor is the presence of extragenital pathology, such as the presence of cardiovascular diseases, including hypertension increases the risk of pregnancy complications 31.4 times, kidney diseases 23.3 times, thyroid disease 14.3 times, and the presence of other diseases 11.1 times.

3. When studying the obstetric and gynecological anamnesis, there was a tendency to have complications during the course of the second and subsequent pregnancies. Violations of the menstrual cycle in the history 8.2 times aggravate the prognosis of pregnancy. Previous cesarean delivery, premature births, miscarriages, and medical abortions also have adverse consequences (OR=3.2; OR=2.2; OR=2.0, respectively).

4. The social factors of the lifestyle include the presence of bad habits in the child's father (OR=10.5), drinking more than 1 cup of coffee per day (OR=10.4), non-compliance with the diet, and especially the use of fast food (OR=6.2), the presence of harmful habits before pregnancy in the mother.

5. The socio-economic and socio-psychological factors include the presence of stress in everyday life, which in turn has an impact on the psychological state of the pregnant woman, increases the risk of pathology during pregnancy (OR=42.6 and OR=40.7, respectively). A low level of financial status also increases 16.5 times the risk of pregnancy complications. Unmarried women had 4.4 times more complications during pregnancy than women with a normal course.

6. Identification of risk factors for pregnancy pathology is important for the development of effective measures for early detection and prevention of these complications.

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Disclosure Statement

The authors have no potential conflicts of interest to disclosure, including specific financial interests, relationships, and/or affiliations relevant to the subject matter or materials included.

Data Transparency

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IDENTIFYING THE MAIN DETERMINANTS THAT HAVE AN IMPACT ON THE LEVEL OF VACCINATION AMONG CHILDREN

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ABSTRACT

Background. Thanks to vaccinations, many infections, including whooping cough, diphtheria, tetanus, poliomyelitis, measles, mumps, rubella, hepatitis B, hemophilic infection, pneumococcal infection, meningococcal infection, rotavirus infection, chicken pox, hepatitis A, papillomavirus infection, etc., can be prevented. According to the WHO research, it was established that if the level of vaccination coverage of the country's population drops by several percents, it creates favorable conditions for the spread of infectious diseases, that the lower the collective immunity, the higher the probability of outbreaks and epidemics.

The Aim. To study and analyze the impact of risk factors on reducing the level of vaccine prophylaxis in the childhood population.

Materials and Methods. This study was conducted using the questionnaire method, for which a questionnaire was developed. Group 1 consisted of 280 children who received a vaccination and group 2 consisted of 180 children who were not vaccinated. The parents of these children were interviewed using the author's questionnaire and gave their consent to use the medical data of the children for scientific research. Non-parametric statistical analysis for two independent sample populations was used to compare median values Mann-Whitney test. Fisher's test was used to compare proportions.

Results. During the study, it was found that the most frequent reasons for parents' refusal to vaccinate their children were: religious views of family members 2.4 times increase the risk of non-vaccination in children; in single-parent families where the parents are divorced, children did not receive any vaccination 2.6 times more than in full-parent families; unfinished average of 35.7 times and lack of education 24.1 times increase the impact on the lack of vaccination in children.

Conclusions. We identified the following risk factors that influence the vaccination rate, namely: demographic, socio-economic, biological and socio-psychological.

Keywords: *vaccine prevention, statistics, infectious diseases, risk factors.*

INTRODUCTION

Vaccination, as an integral part of the public health system, has proven to be the most effective tool in the fight against infectious diseases. So far, scientists have not invented something more effective than immunoprophylaxis for this [1].

Today's global issue in Ukraine is to ensure the protection of the population from outbreaks of controlled infectious diseases through timely planned immunization of the country's residents. That is, the development of modern programs for im-

munization of children and adults is one of the urgent and priority directions of the public health system. In the contemporary society, there are widespread misconceptions and ignorance about vaccination among parents. In Ukraine, parents unreasonably refuse vaccinations, which leads to outbreaks of deadly diseases. In 2020, the WHO for the first time included vaccine refusal in its annual list of threats to humanity. Therefore, the study studied the dynamics of this phenomenon in order to develop ways to combat it [1; 2].

According to a survey by the United Nations Children's Fund (UNICEF), mistrust of vaccinations in general and vaccine manufacturers, mistrust of medical professionals who promote vaccinating children and the conditions for storing vaccines, as well as fear of diseases and side effects from vaccinations are the main reasons for

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refusal of vaccination by the latter for years [3; 4]. One of the main risk factors for the decrease in childhood vaccination in the recent years is the full-scale military invasion of the Russian Federation into Ukraine. The level of coverage of preventive vaccinations in Ukraine before the war against most vaccine-controlled infections lagged behind the WHO recommended 90–95%. Currently, according to the Ministry of Health of Ukraine, the analysis of preventive vaccination coverage in the regions that provided information in 2022 indicates an even lower level of preventive vaccination coverage [2; 5]. In connection with the active hostilities on the territory of Ukraine, in some regions it is impossible to provide vaccination due to destroyed hospitals, warehouses, the inability to provide logistics, etc., therefore the rates of coverage are low [6].

Vaccine prophylaxis is recognized as one of the most successful and cost-effective measures of all existing public health measures. However, it is difficult to find a medical topic that would generate so much controversy among the population. Therefore, in recent years, anti-vaccination sentiments have sharply increased in Ukraine, and the number of vaccinated children is steadily decreasing. Doctors are a major source of both negative and positive attitudes toward vaccination, as well as a source of misinformation. Shortages and interruptions in the supply of free vaccines in hospitals also have a significant impact on vaccination coverage [6; 7].

The aim of the work was to study and analyze the impact of risk factors on reducing the level of vaccine prophylaxis in the childhood population.

Materials and Methods

460 children who were divided into two groups took part in the study. Group 1 consisted of 280 children who received a full course of vaccination or were partially vaccinated, and group 2 consisted of 180 children who were completely unvaccinated. All children are studying at Horodyschenskiy pre-school educational institution No.1 "Dzhereltse" of Cherkasy region; Horodyschensky Economic Lyceum of the Horodyschenska District Council of Cherkasy Oblast; Horodyschensky pre-school educational institution No.2 "Zirochka" of Cherkasy region. All children were under medical supervision at the KP "Horodyschenskyi District Center of Primary Health Care" of Horodyschenskyi District Council of the Cherkasy region.

The study of data on the state of vaccination prophylaxis of children was also carried out by the

method of copying data from the form of primary accounting documentation No.112/o "History of child development".

The questionnaire "Regarding the state of vaccine prevention of infectious diseases in children and determinants that have an impact on the level of vaccination of the childhood population" was used to survey the people who participated in the study. Parents of all children included in the study groups provided written informed consent.

Non-parametric statistical analysis for two independent sample populations Mann-Whitney test was used to compare median values. Fisher's test was used to compare proportions.

In order to determine the risk factors of the lack of vaccine prophylaxis in children, a logistic regression analysis was used with the calculation of the odds ratio (OR) of the occurrence of the event according to the z-criterion, and their 95% confidence interval (CI) was determined using the program package "MedCalc Software" version 22.023 (MedCalc Software Ltd, Belgium). The difference in the parameters of the four hollow tables was considered statistically significant at $p < 0.05$ and if the CI did not contain "1".

Results and Discussion

The study using a questionnaire made it possible to study biological, demographic, socio-economic and socio-psychological risk factors for the lack of vaccinations in children of different ages. Interviewed parents were asked questions about contraindications to vaccinations and subjective reasons for refusing vaccinations (*Tables 1–3*).

We found that children in families with three children are 5.7 times more likely to be unvaccinated than in families with fewer children. The religiosity of family members increases the risk of lack of vaccination in children by 2.4 times. The risk factor for refusing vaccination is the level of education, namely incomplete secondary education 35.7 times and lack of education 24.1 times increase the impact on lack of vaccinations in children. The labor activity of people also indirectly depends on the availability of education. Therefore, if family members do not work, the child will not be vaccinated 2.9 times more often, and if family members are engaged in physical labor, then 16.7 times more often. The social risk factor for refusing to vaccinate a child is the income per family member, when it is one minimum wage, it is 30.5 times more than that of vaccinated children. Social risk factors, namely bad habits, also increase the chances of a child not being vaccinated (*Table 2*).

Table 1. Demographic and socio-economic risk factors for lack of vaccination in children of different ages

Risk factor	Output data (patients)				OR	95% CI	p
	a	b	c	d			
Number of children in the family							
Three children in the family	20	160	6	274	5.7	2.2–14.5	0.0030
Religiosity	148	32	185	95	2.4	1.5–3.7	0.0002
Belonging to religious organizations	78	70	85	100	1.3	0.9–2.1	0.2207
Education							
Medium special	43	133	38	242	2.0	1.3–3.3	0.0035
Average	47	129	29	251	3.2	1.9–5.2	0.0001
Unfinished secondary	20	156	1	279	35.7	4.8–269.0	0.0005
No education	14	162	1	279	24.1	3.1–185.0	0.0022
Marital status							
Divorced	43	136	30	250	2.6	1.6–4.4	0.0002
Employment							
Does not work	29	151	17	263	2.9	1.6–5.6	0.0007
Physical activity	102	49	31	249	16.7	10.1–27.7	0.0001
Financial income per family member							
One minimum wage per family member	111	69	14	266	30.5	16.5–56.5	0.0001
Smoking in the family	89	91	64	216	3.3	2.2–4.9	0.0001
Consumption of alcohol	155	25	72	208	17.9	10.8–29.5	0.0001
Once a week	14	141	1	71	27.7	3.6–212.8	0.0014
Weekend	74	81	15	57	3.5	1.8–6.6	0.0002

Notes: a – children with sign and not vaccinated; b – children without sign and not vaccinated; c – children with sign and vaccinated; d – children without sign and vaccinated.

Table 2. Biological risk factors for lack of vaccination of children

Risk factor	Output data (patients)				OR	95% CI	p
	a	b	c	d			
Child's health condition							
Is the child healthy?	112	68	233	47	0.3	0.2–0.5	0.0001
Perinatal risk factors							
Complicated pregnancy	27	153	1	279	49.2	6.6–365.8	0.0001
Presence of diseases in the child							
Respiratory organs	23	157	21	259	1.8	0.9–3.3	0.0007
Cardiovascular system	27	153	12	268	3.9	1.9–8.0	0.0001
Musculoskeletal system	11	169	1	279	18.0	2.3–141.9	0.0057
Immune system	10	170	11	269	16.4	2.1–129.3	0.0079
Genitourinary system	24	156	19	261	42.9	5.7–120.0	0.0002
Endocrine system	36	144	1	279	1.8	1.1–3.0	0.0232
Suffered operations, injuries	47	133	52	228	1.9	1.2–3.0	0.0031
Does the child take any medications?	46	134	35	245	2.4	1.5–3.9	0.0004
Father's temperament							
Phlegmatic	33	147	31	249	1.8	1.1–3.0	0.0225
Melancholic	37	143	18	262	3.7	2.0–6.8	0.0001
Mother's temperament							
Phlegmatic	44	136	26	254	3.1	1.8–5.3	0.0001
Melancholic	23	157	14	266	2.7	1.3–5.5	0.0038

Notes: a – children with sign and not vaccinated; b – children without sign and not vaccinated; c – children with sign and vaccinated; d – children without sign and vaccinated.

Biological risk factors for parental refusal of vaccinations are pregnancy complications 49.2 times more often than in families without complications. Diseases of respiratory organs in children increase the refusal of vaccinations by 1.8 times, cardiovascular diseases by 3.9 times, diseases of the musculoskeletal system of the child – 18 times, diseases of the genitourinary system – 42.9 times, and taking medication due to various diseases increases the risk of parents refusing to vaccinate their children – 2.4 times.

Among children who were not vaccinated, the following risk factors were determined, due to which the child's mother was not vaccinated with any vaccine or was partially vaccinated, the main ones are: allergic reactions OR=71.1, religious views OR=67.0, the largest share is mistrust of vaccines OR=84.1 and lack of awareness about vaccines in general OR=6.0. The factors of lack of vaccination or partial vaccination of the child's father are also determined: allergic reactions OR=76.0, religious views OR=44.1, the most significant factor is mistrust of vaccines OR=128.0, factors are insufficient information about vaccines OR=111.1.

During the study, we found that these risk factors have a significant impact on the decrease in the level of vaccination among children in Cher-

kasy region, where this study was conducted. If we compare the vaccination coverage of the child population in Cherkasy region with all – Ukrainian indicators, for example, for the last year, then it can be noted that some levels are lower in the region. Such as vaccination against measles, rubella and mumps in children in the first year of life, which is 86.2%, while the all-Ukrainian indicators are 92.4% and vaccination against these infections in children 6 years in the region is 86.3%, while in Ukraine 87.3% [2].

But still, most indicators are higher than in Ukraine. Although the indicators of vaccination coverage are higher than all Ukrainian, they are insufficient for the formation of stable collective immunity to fight infectious diseases, which should be 95%.

Among the 280 children who were vaccinated according to the national vaccination calendar, they were additionally vaccinated against the following infections: against meningococcus 78 (27.8%), pneumococcus 56 (20.0%), influenza 128 (45.7%), chicken pox 10 (3.5%), hepatitis A 12 (4.2%), rotavirus infection 22 (7.8%). That is, there is a low proportion of children who are vaccinated with additional vaccines, even against infections that can threaten life.

Table 3. Socio-psychological factors of the lifestyle of parents, unvaccinated children

Risk factor	Output data (patients)				OR	95% CI	p
	a	b	c	d			
Is the mother vaccinated?	133	47	279	1	<0.0	–	0.0001
Reasons for lack of vaccination or incomplete vaccination of the child's mother							
Allergic reactions	18	29	1	279	71.1	22.1–134.0	0.0001
Religious views	23	24	1	279	67.0	34.5–206.0	0.0001
Distrust	26	21	1	279	84.1	44.0–267.0	0.0001
Insufficient awareness	1	46	1	279	6.0	0.3–98.0	0.2053
Is the father vaccinated?	152	28	279	1	<0.0	–	0.0001
Reasons for lack of vaccination or incomplete vaccination of the child's father							
Allergic reactions	6	22	1	279	76.0	8.7–160.1	0.0001
Religious views	13	15	1	279	44.1	0.6–193.4	0.0001
Distrust	23	5	1	279	128.0	123.0–953.0	0.0001
Insufficient awareness	8	20	1	279	111.1	13.0–973.0	0.0001
Awareness of additional vaccines not included in the national calendar	96	84	279	1	<0.0	–	0.0001
Uncertainty about the safety of vaccines	63	117	1	279	150	20.1–196.0	0.0001
Not interested in vaccine safety	84	96	1	279	244	33.3–777.0	0.0001

Notes: a – children with sign and not vaccinated; b – children without sign and not vaccinated; c – children with sign and vaccinated; d – children without sign and vaccinated.

Parents who vaccinate their children showed a different proportion of trust in the quality of vaccines depending on the country of manufacture. Thus, 100% trust was expressed in France and Belgium, 67.8% in the USA, 36.4% in the Republic of Korea, 33.9% in Bulgaria and 29.6% in India.

Socio-psychological risk factors for the lack of vaccine prevention are insufficient awareness of communities about vaccine safety, vaccination points and availability of vaccines in hospitals, storage and transportation conditions, and vaccine safety.

If the tendency to refuse vaccination continues in the future, the scale of the problem will grow. The growth of whooping cough has already increased, and real epidemics are possible in the future. And if we let the problem go, we'll be back in the Middle Ages, when infections were the main cause of high mortality and short life expectancy.

Conclusions

All the given reasons for refusing vaccinations with one or another vaccine are scientifically unfounded and groundless. A detailed analysis of the reasons for refusal of vaccination and proof of the necessity and expediency of vaccination makes it possible to cover a larger number of the population with mass vaccination and protect a significant number of people from serious infectious diseases. All of the listed risk factors require the im-

provement of the social, financial, and educational status of families, prevention of harmful habits and measures to raise public awareness.

Demographic and socio-economic risk factors for not vaccinating children are the presence of three or more children in the family, the religiosity of the family and belonging to religious organizations, divorce, i.e. incomplete family, average and low level of education, physical work of parents, bad habits, bad financial situation.

The processes of vaccine prophylaxis in children are influenced by such biological risk factors as complicated pregnancy of the mother, diseases of various organs and systems, and the temperament of parents also affects the decision on the issue of vaccination of children.

DECLARATIONS:

Disclosure Statement

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MEDICAL ASSISTANCE IN DYING FOR PALLIATIVE PATIENTS IN DIFFERENT COUNTRIES OF THE WORLD: LESSONS ON EUTHANASIA LEGALIZATION

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ABSTRACT

Background. The practice of countries in legalizing euthanasia is useful for other countries that have not yet allowed Medical Assistance in Dying (MAiD). Palliative patients in these countries have varying levels of access to medical care, including adequate analgesia. Medical care in many countries does not meet the needs of palliative patients, and systems of palliative and hospice care are often poorly developed. MAiD can be an alternative to the suffering of palliative patients at the end of life.

Aim. Analysis of legal, social and financial aspects of euthanasia legalization in different countries of the world.

Materials and Methods. The method of system analysis, comparative method and bibliosemantic method were used for the research.

Results and Conclusions. The path to the legalization of euthanasia begins with a wide public debate. Important is the opinion of medical professionals, who are usually divided into two camps: those who deny the necessity and humanity of euthanasia, as well as those who advocate legalization to end the suffering of their patients, seeking to satisfy their persistent and conscious desire to exercise their "right to die". Countries take different paths and at different speeds to legalize euthanasia. The difference between the models of legalized euthanasia lies, first of all, in its permitted type (passive or active), distribution to different age categories of hopeless patients (in particular, to children), to incapacitated patients with cognitive disorders. Active euthanasia is allowed in such European countries as the Netherlands (since 2001), Belgium (since 2002), Luxembourg (since 2009), Spain (since 2010), Switzerland (since 2011). Since these years, there has been a change in the attitude towards medically assisted death of the European Court of Human Rights, which previously categorically regarded euthanasia as intentional murder. In all countries that have legalized euthanasia, an active discussion continues regarding the rules for its implementation. A common feature of countries that have already legalized euthanasia is the approval of the procedure by at least a third of medical professionals.

Keywords: *medically assisted suicide, suicide tourism, Quality of Death Index, suicide of critically ill palliative patients, right to life, right to die.*

INTRODUCTION

In many countries, the proportion of elderly people in the population is increasing, and with it the incidence of cancer and other diseases that lead to a painful death. To compare countries according to the organization of the best dying, the

Quality of Death Index (QDI) was developed in 2010 [1], which assessed the availability and quality of end-of-life care in 40 countries according to 24 indicators. In 2015, the QDI already evaluated 80 countries using 20 quantitative and qualitative indicators in five categories: palliative environment and health care, human resources, accessibility of health care, quality of health care, and level of community involvement [2]. The 2010 country assessment identified Great Britain as the best country for dying, thanks to a comprehensive national policy, broad integration of palliative care into the national health care system and the development of the hospice system [3].

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Great Britain also took the 1st place in 2015. The 2nd place in the list was taken by Australia, and the 3rd by New Zealand. The USA was on the 9th place, Canada on the 11th. The leading countries of the rating noted an effective national policy of palliative care, a high level of public spending on health care services, developed educational programs of palliative medicine, large charitable contributions to Palliative and Hospice Care (PHC) institutions, wide availability of opiates for pain relief, public awareness of PHC problems.

The state of PHC with all aspects of care for palliative patients, ensuring their rights and meeting their needs, depends to a large extent on the funding of national PHC programs. Approaches to funding the best national PHC systems vary: in the UK, the main source of funding is philanthropy. Australia, Denmark, Belgium and Ireland fund 80–100% of palliative patient costs with public funds. The Ukrainian model of package financing of PHC also gives hope for improving the rating of the country [4]. The models of PHC organization are also different. For example, Panama has integrated palliative care into its primary care services, and Mongolia is rapidly increasing the number of hospices. The availability of narcotic painkillers (and medical cannabis in particular) correlates with the country's place in the rating [5; 6]. Pain relief is one of the basic needs of palliative patients [7], but only 33 of the 80 countries in the 2015 ranking had opiates freely available.

The calculation of the QDI is related to the determination of the burden of diseases and the prevalence of severe disabling diseases [8]. In 2015, the qualitative weight of the burden of diseases in the defined QDI was 60%. Another important factor in the development of national PHC systems is orientation to patient needs [9]. Social and military crises, on the contrary, inhibit the development of these systems [10]. Important for development is a wide list of palliative diseases recognized by states [11; 12]. In the 2015 QDI ranking of countries, Ukraine ranked last in Europe with a score of 25.5 points, and the 69th out of 80 places in the overall ranking. The indicators of such countries as India (26.8 points), Colombia (26.7 points), Ethiopia (25.1 points), and China (23.3 points) were close to the indicator of Ukraine. In order to understand which factors are decisive for the development of the PHC system of countries to ensure the dignified and painless dying of palliative patients, an analysis of the practices of legalizing euthanasia in other countries of the world is necessary.

The aim of the study was to analyze the legal, social and financial aspects of the legalization of euthanasia in other countries of the world.

Materials and Methods

The research used methods of systematic analysis, comparative and bibliosemantic, with a search for sources on PubMed, Google and Google Scholar using the keywords "palliative and hospice care", "legalization of euthanasia", "foreign experience", "medically assisted death", "suicides of palliative patients", "quality of death index" in Ukrainian and English. In connection with the theoretical approach to the research, bioethical examinations of the research materials were not conducted. Statistical methods were also not used.

Results and Discussion

Palliative care is intended neither to delay nor hasten death. But a significant number of patients experiencing intense chronic pain at the end of life is pushing for an alternative to self-initiated gradual dying – Medical Assistance in Dying (MAiD). Euthanasia is legalized in Sweden, Netherlands, Belgium, Switzerland, Finland, Germany, Chile, USA, Canada, Israel, Mexico. Public discussions about death had a significant influence on countries' decisions to legalize euthanasia [13]. The willingness of countries to legalize euthanasia also depends significantly on the religiosity of the population [14]. If a country has a neighboring country that allows euthanasia, or the country's population has sufficient income for medical suicide tourism, palliative patients travel to other countries to end their lives with dignity.

Legislators of countries that were moving towards the legalization of euthanasia, to a certain extent, added to the opposition of the international law system. The position of the European Court of Human Rights regarding euthanasia was categorically condemning before its legalization in many countries of the world. The court saw euthanasia as a violation of Article 2 (right to life) of the European Convention on Human Rights [15]. However, the evolution of legal interpretations changed the attitude: the "right to die" became an important component of the right to life. In the field of palliative medicine, it is more often called "the right to a dignified death". Titko E.V. & Deineko O.V. (2020) note that citizens will not resort to euthanasia tourism if the right to euthanasia is enshrined in the legislation of their countries. Switzerland has become the most attractive country for foreigners with liberal conditions for performing euthanasia [16]. The Swiss canton of Zurich is the most famous area where euthanasia is widely used

for foreigners. The Swiss clinic "Dignitas", opened in 1998, is called the "Mecca of suicide tourism". But the US citizens sometimes go to Mexico for MAiD. And this is despite the fact that euthanasia has already been legalized in some states of the country. Such a choice may be related to the fact that upon returning home, persons who accompanied their relative to the MAiD site may face criminal prosecution. It will be easier to prove guilt if the suicide took place on the territory of one's own country.

From a legal point of view, euthanasia is "the action or inaction of a doctor at the request of his patient in order to end his suffering, the result of which is the realization of the right to a dignified death, provided that the patient understands and is aware of his actions in compliance with the law" [17]. A dignified death in Ukraine cannot be provided by active euthanasia. Thus, Clause 4 of Article 281 of the Civil Code of Ukraine limits this right as follows: "It is prohibited to satisfy the request of an individual to end his life". Article 52 of the Law of Ukraine "Fundamentals of the Legislation of Ukraine on Health Care" defines: "Medical workers are prohibited from performing euthanasia – intentionally hastening the death or mortification of a terminally ill patient in order to end his suffering". Similarly, Ukrainians are often deprived of the right to a dignified death without pain [6; 8; 18]. In addition, Ukrainian society is not ready to start a dialogue about the possibility of legalizing euthanasia [14]. Therefore, for Ukraine and other countries with low QDI, the experience of countries that have already legalized QDI is useful.

In the Netherlands, MAiD is legal for patients from the age of 16. From 12 to 16 years of age, the consent of parents or guardians is required for this procedure. Since 2005, in exceptional cases (most often in the terminal stages of cancer), the Groningen Protocol has allowed neonatal euthanasia (for babies under 1 year old). Children aged 1–12 years are not eligible for MAiD [19]. Decisions about MAiD are made by consensus of several doctors. After the legalization of euthanasia in 2001, society continues to actively discuss the rules of the procedure. In the Netherlands, legislators take the position that the state "is obliged to protect citizens from making decisions that do not correspond to their best interests, for example, the decision to die, when "unbearable suffering" can be reduced so much that the person gives up the desire to end suffering by death" [20]. Therefore, doctors should offer the patient alternatives to MAiD

and allow time to test them. Legislators in Canada, where patients are allowed to decide for themselves whether to try other methods of palliative medicine before deciding on MAiD, think differently. Canadian doctors only give a patient with a clear intention to resort to MAiD the choice: to perform a lethal injection, or to allow the patient to perform such an injection himself. Also, the Canadian doctor must make sure that the patient answers confidently and uniformly when asked about the choice of MAiD. Therefore, the question about MAiD should be asked several times. A guardian cannot ask a doctor for MAiD for an adult incompetent patient, but the parents or guardians of a minor terminally ill child can request it [21]. For adults, the right to MAiD is limited if the palliative condition is due to one mental illness with a cognitive disorder that does not allow you to confidently express your wish for MAiD [22].

In Canada, parents of children with palliative diagnoses are willing to discuss the feasibility and practical aspects of MAiD with doctors and research scientists. In a 2017 survey of almost 2,000 parents, 46% called children's MAiD acceptable. The percentage of similar answers varied in subgroups of interviewees depending on the diagnoses offered for discussion and the age of the children. A high percentage of acceptance of euthanasia was also demonstrated by pediatricians and nurses of children with palliative diagnoses. Doctors' refusal to consent to the appointment and conduct of MAiD was associated with their religiosity, disagreements with colleagues on specific cases and the very attitude to MAiD, the burden of observing patients dying [23].

In the legalization on euthanasia in Canada, the discussion of the problem in the mass media played a significant role. From 1972 to 2016, Canadian newspapers in English and French discussed the role of doctors in the care of critically ill patients and their possible involvement in MAiD, legal and political aspects of legalization (appeals to the Supreme Court of Canada in euthanasia cases, legal cases against Canadian doctors and Dr. Kevorkian, parliamentary legalization), the attitude of Canadians to MAiD. Crumley E.T. et al. (2019) conducted an analysis of 813 newspaper articles during this time, and divided the 44 years of media discussion before the legalization of euthanasia into three periods: 1) awareness of the problem, 2) anxiety and euphoric enthusiasm, and 3) awareness of the price of significant progress [24]. The researchers concluded that, based

on the results of the random sample, there were more positive articles about MAiD. They explained the victory of euthanasia supporters, including the decline of religion in Canada.

One of the problems that Canada was dealing with after the legalization of MAiD was the insufficient level of professional training of medical workers to work in the PHC system. A survey of 452 physicians, nurses, administrators, and volunteers working in Canada's PHC system one year after euthanasia was legalized revealed a need for more professional issues specific to palliative care in training programs and a lack of funding for such training programs [25].

While active euthanasia is allowed in the Netherlands, Belgium and Canada, passive euthanasia is allowed in Sweden, France and Finland [17]. In Ukraine, passive euthanasia is not allowed *de jure*, but *de facto* it is often performed when a physician decides to end life support. In low- and middle-income countries, health care facilities are often under-resourced, so doctors prefer to save available drugs for patients who can be saved. Arguments about the high risk of professional error at the moment of brain death, after which disconnection from resuscitation equipment can no longer be qualified as intentional murder, are unconvincing. When it comes to diagnosing brain death, the majority of doctors in the world are in approximately the same conditions [26]. But it was this argument that was the main one when the Ukrainian parliament (Verkhovna Rada) refused to legalize euthanasia in 2003 and 2010.

Belgium became the second country in the world to decriminalize euthanasia, after the Netherlands. But even after legalization in 2002, society continued to discuss the problems associated with it: obtaining donor organs, euthanasia of infants, the illegal practice of euthanasia alongside the legal one [27]. The latter accounted for 4.5% of all deaths in the country after legalization. A similar practice was widespread in the country even before legalization. But the activity of legislators regarding legalization was also high: in the period 1984–1996, 9 draft laws on legalization were submitted to the Belgian Parliament. The population of Europe at that time gradually changed its attitude towards euthanasia for the better. During 1981–1999, the number of positively disposed citizens increased by 22%. In 1996, the Federal Advisory Committee on Bioethics was established in Belgium, which studied public opinion but did not make any recommendations. The first criminal investigation into illegal

euthanasia in the country began in 2000 against two doctors. But they were not punished because the sentence was announced in 2003, after legalization, and the legalization law applied retrospectively to cases of euthanasia. Legalization was accelerated by the absence of Christian Democrats in the country's government.

Before the procedure, the patient must be informed about his/her condition. The wish for euthanasia must be certain. There should be several conversations with the doctor. The physician must be satisfied that there are no reasonable alternatives to euthanasia. Each patient's euthanasia should be discussed with another physician, nurse, and the patient's relatives/caregivers. The patient should be allowed to discuss euthanasia with whomever he chooses. The activities of doctors who agreed to euthanasia are audited. In case of non-fulfillment of the procedure, the commission forwards the audit results to the prosecutor's office.

There is no age limit for euthanasia in Belgium. Under special conditions, it can be prescribed even to newborns. For euthanasia of infants, an examination by a psychologist or psychiatrist is mandatory. For adults, such consultation is only desirable. The first case of euthanasia of a minor was registered only in 2016. Therefore, the permission for euthanasia of infants is more of a political step, but does not have significant consequences.

In Belgium, euthanasia of patients with dementia is not allowed. A survey of neurologists in the country in 2019 showed that 77% of respondents approve of the law on euthanasia, but 65% are against extending the law to patients with dementia [28]. Another survey of Belgian family doctors in the same year [29] showed that 59% were against extending the practice of euthanasia to patients with terminal stages of dementia, if these patients cannot clearly express their will. At the same time, non-religious doctors supported such an expansion twice as often as their religious colleagues. 72% of GPs reported that they fear pressure from relatives if care-givers are allowed to claim MAiD for their incapacitated relatives.

Only active euthanasia is allowed in Belgium. Stopping treatment to end life is prohibited. The wording of the law "in the absence of a reasonable alternative" for euthanasia is too vague and has been criticized for many years. Even after legalization, half of all euthanasia cases are not registered by doctors as euthanasia. In the early 2010s, 80% of euthanasias occurred in the Belgian region

of Flanders. There is concern in Belgian society about the high risk of involuntary euthanasia. It is partly related to the removal of donor organs, which is permitted in the country, without the prior consent of the deceased. But within the period of 2007–2015, only 2% of donor lungs were obtained from patients after euthanasia. Many patients who turn to doctors to end their lives have cancer that is a contraindication for organ transplantation. Concerns may become more grounded in the growing number of young people seeking euthanasia. The shortcomings of the practical implementation of the Belgian law on euthanasia should be taken into account by other countries.

In the US, there is considerable variation in state-to-state law on key aspects of life and death. Euthanasia is legalized in Oregon, Montana, Washington, California, and Vermont. The laws of the states of Oregon and Washington allow medically assisted suicide only for patients whose life expectancy does not exceed 6 months [30]. Many right-to-die advocates have preferred to expand the list of conditions in which MAiD is possible, particularly in cases where terminally ill patients show a persistent and rational desire to die but are physically unable to end their own lives. Refusal to help such patients was considered by many to be "torture of inaction." In Europe, the USA and Canada, some married couples expressed a desire to die together, sometimes committing suicide at the same time. This practice raised the issue of allowing MAiD of healthy people before the society. Of course, it is impossible to give permission for the procedure to mentally ill people during psychosis. But if the patient shows a persistent desire to die, no one can prevent him from committing suicide on his own. Unfortunately, in this case, the way to end life can be painful.

In the US, euthanasia was first legalized in California in 1977, with the adoption of the world's first right-to-die law. The life expectancy of a patient with an incurable disease who is given drugs for self-enduring should not exceed 6 months. The patient must be of legal age, able to act, understand his diagnosis, prognosis and consequences of the decision made. The decision to provide medication is made by several physicians.

A number of social and medical ethical problems are associated with euthanasia. For example, how to evaluate a patient who is on long-term opiates due to excruciating chronic pain caused by an incurable disease. Soh T.L. et al. (2016) [31] convincingly refute the popular thesis that "iatrogenic

loss of consciousness equals loss of personality and death". Their work is based on the analysis of empirical data. The study demonstrates the refutation of a false but popular philosophy by the methods of evidence-based medicine. Terminal sedation can lead to the death of the patient unintentionally as a side effect [19]. Opponents of euthanasia claim that the availability of euthanasia reduces the demand for palliative care, that doctors can treat palliative patients inappropriately: why treat a palliative patient for a long and difficult time, if you can just kill him. Proponents of euthanasia respond to this: the doctor's wishes are secondary, the wishes of the patient, who considers his suffering unbearable and asks for it to be stopped, must be respected. Opponents of euthanasia argue that children under the age of 12 are not capable of giving informed consent to their own death (euthanasia is legal from the age of 12 in the Netherlands), just as they are not allowed to vote in elections, join the army, marry, or have sex. Likewise, children 12 years old are not given the right to allow their own sterilization. Proponents of euthanasia respond to this: one cannot compare civic and social immaturity, and even a potential life without offspring to a life with constant excruciating pain.

The problem of euthanasia also intersects with the issues of suicide. The experience of Northern Ireland, which had the highest suicide rates in the United Kingdom in 2014–2015 (1.7% of all deaths, or 16.5 suicides per 100,000 population in 2015), shows that suicides are more male (3/4 in 2015) that most suicides are committed at the age of 25–35 [32]. The use of methods of evidence-based medicine was transferred to the field of euthanasia precisely from the pool of research on suicides [33; 34]: errors in statistical evidence are not associated with falsifications, but with the mischaracterization of events in the criminal process. Similar qualifications in the criminal legislation of different countries are different, as well as criminal responsibility. Thus, for example, in the Criminal Code of Switzerland, euthanasia is in the section "Murder" (Homicide, article 114). For murder at the request of the victim, at his own genuine and persuasive request, his own and persistent request, the penalty is imprisonment for not more than three years or a monetary fine. At the same time, the term of imprisonment for inciting suicide or aiding suicide may be up to five years of imprisonment [35]. In some countries, high criminal liability is also provided for actions associated with suicide. For example, in Norway, a per-

son who produced drugs that were used for suicide can be punished with up to 5 years of imprisonment [36].

The WHO states that the largest number of suicides in the world is naturally associated with clinical depression [37]. The number of palliative patients among people who have committed suicide is small (0.2–4.6% of total deaths, 1998–2015), but it is still hundreds of times greater than the number of palliative patients who find their way to legal euthanasia. On the other hand, the European Association for Palliative Care states [38] that the majority of representatives of professional organizations of PHC systems of different countries during a survey in 2016 believed that euthanasia and MAiD should not be included in the list of palliative medicine procedures. Euthanasia is not included in the "White Book of Palliative Medicine" [39]. A similar opinion has been held by the World Medical Assembly for many decades [40]. A similar denial of the "right to die" by medical professionals can be explained by the traditional long-term funding of medical universities and medical associations by religious organizations (e.g., the Roman Catholic Church). A significant part of medical students who study medicine in medical universities for a long time accept the position of the universities, which is dictated by religion.

Historically, euthanasia was frequently practiced in the ancient world. For example, weak children unfit for military service were killed in Sparta, which is known from the works of Plutarch and Thucydides [41–43]. The negative background of euthanasia was also created by the mass murders of the Nazis in the Second World War [44]. That is why only passive euthanasia is allowed in Germany since 2015, and active euthanasia is a criminal offense. From a legal point of view, in addition to active and passive euthanasia, most countries that have legalized it distinguish between "Mercy killing" (when a doctor injects a hopelessly ill patient with an excessive dose of an anesthetic drug, resulting in the desired death) and "Physician-assisted suicide" (when a doctor only helps a terminally ill person to end his life).

It was the last tactic that six times helped the world-famous American pathologist, doctor and supporter of the "right to die" Jack Kevorkian (1928–2011) avoid criminal responsibility for MAiD. In his practice, Jack Kevorkian used a special device "Mercitron" (from English *mercy*) of his own invention, which allowed patients to self-inject medical drugs that stopped the heart. But in

1999, Kevorkian was still sentenced to 25 years for murder after performing a fatal injection recorded on video to a patient who wanted to die but could no longer administer the lethal drug himself [45; 46].

Conclusions

The countries that have already legalized euthanasia have come to this decision in different ways and at different speeds. But there are common features of this process in different countries: the path to legalization begins with a wide public debate, the process of legalization is accelerated due to the activities of dissidents or with an appeal to the courts to protect one's right to euthanasia. At the time of legalization, euthanasia is usually approved by at least a third of doctors who treat critically ill patients. In the countries with sufficient financing of national health care systems, the arguments of supporters and opponents of medically assisted suicide are usually used to argue about the integrity of doctors, the acceptance of the procedure by society, religious prohibitions, the rights of patients to life and death, but the lack of resources of the health care system and the inability to provide seriously ill patients with the necessary medical care, including analgesia for chronic unbearable pain are not taken into account.

The difference in the models of legalized euthanasia concerns primarily its type (passive or active), coverage of different age groups (in particular, children), patients with dementia who cannot consciously and clearly express their desire to end their suffering with medically assisted suicide. The number of suicides of palliative patients is insignificant, and decreases almost to zero after the legalization of euthanasia. But the risks of involuntary euthanasia and violations of the existing rules for conducting medically assisted suicide are high. Suicide tourism is acceptable for wealthy families. A comparison of the legalization situation in the Netherlands, Belgium, Canada and the USA with Ukraine shows that Ukraine is at the beginning of the path to the future parliamentary approval of the procedure.

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**VALEOLOGICAL COMPETENCE OF NON-MEDICAL STUDENTS
AS A TOOL FOR THEIR HEALTHY AND SAFE FUTURE LIFE**

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ABSTRACT

Forming valeological competence of non-medical higher education students is a topical pedagogical problem, which is evidenced by the lack of valeological competence definition in terms of its name and content in the regulatory legal acts of Ukraine and in national standards of higher education, requirements for the degrees of formation of this competence depending on students' educational level, the standard of valeological higher education. Existing textbooks of valeological disciplines are also imperfect. Putting into practice the state policy on preventing socially significant diseases with controlled and nominally controlled risk factors given the importance of both personal and public health, necessitates forming non-medical students' valeological competence. In the review paper forming Valeology as a science, attitude of society and scientific community to it, connection with the legislation of Ukraine on health and health-saving, different approaches to defining the essence of valeological competence, which is formed in the course of studying valeological disciplines, are analysed. A comparative analysis of certain aspects of forming valeological competence of students of medical and non-medical higher education has been carried out. The connections of valeological competence with the culture of health has been considered. It has been concluded that valeological competence is a tool for forming a healthy lifestyle and safe behavior. We also consider it necessary to improve the attitude of society and the scientific community to Valeology through a critical rethinking of the content of educational programs in valeological disciplines. And first of all, this concerns the relevance to exclude from them issues that failed the test in accordance with the criteria of evidence-based medicine.

Keywords: *Valeology, valeological culture, Health Pedagogy.*

Introduction

Valeology is a health science (from the Latin valeo – "to be healthy, strong, robust", from the Greek λόγος – word, teaching, science), which covers numerous aspects of health-saving and health promotion (socioeconomic, medical, environmental and others). The origin of this research dates back to 1980 and is associated with the name of the Soviet pharmacologist Brekhman I. [1]. According to Wikipedia, Valeology is considered as

a pseudoscience [2]. In our opinion, the reason for such phenomenon is the existence of a large number of valeological programmes, textbooks and monographs with dubious issues that draw criticism from researchers and society [4–6]. For example, Reichert K. (2019) [5, p. 10] calls Valeology a "quasi-science" and puts it on a par with astrology, alchemy, numerology, wave genetics, dianetics, phrenology, and homeopathy. Yezhov S. attributes Valeology to "marginal teachings" [6, p. 66].

The problem of forming valeological approaches to a healthy lifestyle came under the spotlight of Amosov M., Apanasenko G., Bekh I., Bekhterev V., Bondarenko O., Brehman I., Vakulenko O., Venedyktov D., Shapovalova T. etc. in

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the 1980s [1; 7–14]. While this research field was being developed by the above researchers, there was no negative feedback from the representatives of scientific community. We associate this fact with the weight of their viewpoints, authority in the academic circles, and the chosen humanistic approach to theoretical research. Some scientists were skeptical about Valeology after the collapse of the Soviet Union because the valeological movement was joined by a number of "healers" whose activities were outside the boundaries of traditional medicine or directly contradicted it (for example, anti-vaccinators, urinotherapists, doctors of Eastern folk medicine, sorcerers and shamans). At the same time, the Ukrainian system of higher education ignored the negative and issued state diplomas in Valeology [15], and the subject "Valeology" was introduced into the curricula of secondary and higher education establishments [16]. In Ukraine, pharmacological and medical Valeology (Sanology) is a part of preventive medicine [17]. Doctors-sanologists are trained at institutions of medical postgraduate education [18]. But the state educational standard of Valeology does not exist yet [19], although there is a certain list of disciplines devoted to a healthy lifestyle.

Among valeological disciplines in Ukrainian educational institutions there are "Valeology", "Fundamentals of Life Safety", "Fundamentals of Medical Knowledge and Health-Saving", "Health Pedagogy", and others. In the light of the competence approach in modern education, a valeological (health-preserving) competence of non-medical students should be formed within these disciplines [20]. Some related disciplines (such as "Occupational Safety", "Fundamentals of Ecology", etc.) cannot be called valeological, because they do not consider all risks to human health, except for those that an individual encounters in industrial production or in terms of environmental pollution, etc. However, the study of these related disciplines also contributes to forming valeological competence and valeological culture, increases the ability to live fully and happily, actively study and work [21], because a person with poor health is considerably limited in his/her opportunities.

The interconnection between health and the ability to socialize, study and work effectively has been studied in the works by such authors as Boichuk Yu., Zamrozevych-Shadrina S., Kuksha N., Leshaft P., Makarenko A., Mikheienko O., Sukhomlynskyi V., Shostak I. [22–27]. In particular, Sukhomlynskyi V. emphasised that the main rea-

son for falling behind in education is poor health, and he called health-saving the most important task of an educator [28]. Makarenko A. used sports and physical culture to strengthen his students' health and reduce the manifestations of their deviant behavior. Therefore, in the modern medical sense valeological competence is health-related; it contributes to health preservation and health promotion.

Valeological competence is universal, necessary for every graduate of higher education institutions, regardless of a study profile [21; 29]. But without a specialised valeological discipline, a graduate of a non-medical higher education establishment can count on only a small level of valeological competence formation acquired thanks to disciplines related to Valeology that also depends on the initial level of knowledge in health and disease prevention issues [30].

There is a significant difference in forming the analysed competence of medical and non-medical students [31; 32], which lies in the fact that students of higher medical education acquire knowledge about health and diseases for their future professional medical activities. In academic circles the discussion of the methods of valeological competence formation has just started, but it is already clear that among students of higher medical education there is an unjustified transfer of the understanding of valeological competence to professional therapeutic and preventive activities [20; 33–35].

In the cultural traditions of many peoples, the desire to be happy is accompanied by the wish to be healthy. Health is one of the greatest personal and social values. The right to health care is guaranteed by the following articles: No.25 of the Universal Declaration of Human Rights, No.12 of the International Covenant on Economic, Social and Cultural Rights, No 6 and 24 of the Convention on the Rights of the Child; No.No. 10, 11, 12 and 14 of the Convention on the Elimination of All Forms of Discrimination against Women, European Social Charter [36]; No.49 of the Law of Ukraine "Constitution of Ukraine" [37]; No.6 of the Law of Ukraine "Fundamentals of the Legislation of Ukraine on Health Care" [38], No.283 of the Law of Ukraine "Civil Code of Ukraine" [39] and a number of other national legal acts.

Of the eight Millennium Development Goals defined by the UN [40], three are devoted to health issues, namely: reducing child mortality; improvement of maternity care; fight against HIV/AIDS, malaria and other diseases. The third

goal of sustainable development of the UN until 2030 is also the goal of health preservation [41], in particular ensuring a healthy lifestyle and promoting well-being for every person of any age [42].

In Ukraine, the term "Valeology" is widely known, while the terms "valeological competence" and "valeological culture" are more typical of scientific literature.

There exist various understandings of valeological competence. In particular, Yasynskyi V. and Zhydetskyi Yu. [43] believe that it is "a component of life competence that manifests in knowledge, values and motives, a valeological position, activities related to health improvement...". Pishchulin V. [44, p. 26] states that forming valeological competence of university graduates means to arm them with knowledge and form skills for a healthy lifestyle. Voronin D. [45] regards valeological competence as "a dynamic trait of the individual that allows to organise and regulate their activities, to evaluate their own behavior, the actions of others, to adhere to their personal beliefs, moral norms and principles despite the influence of external forces". Boychuk Yu. [46] describes the process of forming valeological competence as complex, gradual, continuous, aimed at acquiring knowledge, developing abilities, forming sustainable motivation, beliefs, and willpower against the background of a positive emotional attitude towards the goal of learning. Bondarenko O. and Adeieva O. [47; 48] believe that valeological competence is formed on the basis of a positive attitude to a healthy lifestyle.

We think that forming valeological competence means teaching a person to lead a healthy lifestyle, practice safe behavior and provide pre-hospital emergency care to victims under critical conditions [20].

In our opinion, safe behavior is the one that does not increase the probability of mechanical injuries, burns, frostbite, electric shock, radiation, poisoning, etc. more than the average statistical level of accidents. Dangerous behavior patterns relate to chemical addictions (tobacco smoking, use of drugs and toxic substances, alcohol abuse), unsafe sex (ignoring barrier contraception, frequent changes of sexual partners), sports injuries (in high-achieving sports, extreme sports, neglecting safety equipment), household injuries (ergonomic premises), industrial injuries (when working with moving mechanisms, neglect of safety equipment, lack of personal protective equipment), traffic injuries (when disregarding

traffic rules, driving vehicles in a state of fatigue, intoxication, under bad weather conditions and lighting, driving faulty vehicles), violence (criminal, military, family), poisoning (food, drug, carbon monoxide, methyl alcohol, contact with poisonous plants and animals), radiation (when using nuclear weapons, staying on territories, premises contaminated with radioactive nuclides, consumption of contaminated food and water, medical procedures and frequent long air flights), staying in a state of strong long-term stress (during conflicts, being in a combat zone).

Our viewpoint coincides with the opinions of other researchers [49–51], who emphasise that a safe model of behavior also includes the refusal of unnecessary hazards to health and life, namely: extreme and combat sports, scuffles, engagement in high-risk professions (with radiation, poisonous chemical and explosive substances, military service, law enforcement, fire safety, rescue, high-altitude and underwater work, etc.). Therefore, when forming safe behavior models, it is important not to neglect safety rules. But it is relevant to describe such behavior with the words "to take safety measures", "to avoid unnecessary risks", etc., that is, to avoid negative wording.

Some of the emphases we have made in defining the content of health-saving and safe behavior are particularly important. For example, the incompatibility of a healthy lifestyle with alcohol and drug addictions. According to the WHO [52], non-use of psychoactive substances means a refusal to use them and a special (firm and conscious) attitude of the inadmissibility of experiments with psychoactive substances. Having such beliefs, an individual should never, regardless the circumstances, smoke or use narcotic substances for recreational purposes. Human behavior in various typical situations, when there is a hazard to health and life, is described by models, typical scenarios. The probability of risk to life and health in such situations is known thanks to statistical studies [53]. The number of people who abuse psychoactive substances is extremely high, and the consequences in terms of personal and population health, add to the financial burden on the health care systems of countries that is projected for decades to come. Therefore, any detailed analysis of the content of a healthy lifestyle concerns the non-use of psychotropic substances.

An indicator of a person's successful health-saving is his/her feeling of happiness. And there even exists such an opinion that effective prevention enables avoiding unnecessary communica-

with doctors. Instead, our understanding of a healthy lifestyle presupposes a person's mandatory rational interaction with medical workers, implementation of doctors' recommendations on mandatory health care measures, in particular on vaccination according to the national calendar of vaccinations, harmony of relations with the outside world (avoiding conflicts, excessive stress, detecting and timely regulation of emotional imbalance), refusal of unnecessary hazards that are not related to professional duties. Doctors and teachers agree that valeological competence allows you to treat your own health carefully, as well as other people's health, your students, strengthen health, and create a health-preserving educational environment [54]. Such an understanding borders on such competences of higher medical education students as diagnostic, therapeutic and preventive ones aimed at patients [55; 56]. But university students of absolutely all specialties need valeological competence first of all for their own well-being, as well as for good health.

Modern researchers consider valeological competence as a component of health culture. For example, Shostak I. [57] believes that health culture lies in the ability to lead a healthy lifestyle, correlates with the level of health, and should be used in sanitary and educational work as an integral part of the teacher's professional skills. Boychuk Yu. [58] calls valeological culture a part of general culture and emphasizes the unity of biological, psychological, social and spiritual factors that determine the way of life and the humanistic meaning of an individual's existence. Adeeva O. [48] considers valeological competence a component of the teacher's valeological culture, which indirectly affects public health through students. Melnyk Yu. [59] defines health culture as a set of pedagogical, medical, psychological, and philosophical knowledge, but it is important that such a definition applies to secondary school students of lower forms. The author believes that with age (as for high school students and university students), the value component and motivation are gets more and more important, and the culture of health becomes a multidimensional and complex phenomenon. The ways of its formation are also expanding. Bezugla L. [60] thinks that the formation of valeological culture is mostly influenced students' autonomous work, in particular, their participation in recreational and rehabilitation processes. In this way, she emphasizes

the process of restoring health, forming commitment to a healthy lifestyle based on one's own negative experience of losing health. Instead, Bulych Ye., Hryniova M., Zhabokrytska O., Muraviov I., and Yazlovetskyi V. [62; 63; 64, p. 6, 7] believe that the object of Valeology is a mostly healthy person.

In case of considering valeological culture as a part of general culture, it is important to see the connection with education. In this regard, Kyrylenko S. [64, p. 8] thinks that the culture of health is an integrated quality of an individual and an indicator of his/her good breeding. The level of health culture, according to the researcher, correlates with the level of valeological knowledge and skills, as well as determines the behavior in relation to other people's health. Thus, determining the ability to lead a healthy lifestyle in the context of forming health culture requires the study of a wider range of issues concerning a person's interaction with other people.

Conclusions

Within our research, we focus on competence, as the ability to realise the biological (genetic) potential of an individual to lead a healthy life, to cure existing diseases or reduce their manifestations, to prevent the appearance of new illnesses, injuries, and premature death. In view of this, we consider a person as a biological object with complex physiology, mental activity, high adaptation reserves, as well as with capabilities of self-regulation and prevention of self-destructive behavior. The study of valeological culture is the perspective of our further investigations.

Valeological competence is a tool for forming a healthy lifestyle and safe behavior. It is necessary to improve the attitude of society and the scientific community to Valeology through critical rethinking of the content of educational programmes in valeological disciplines. First of all, this concerns the relevance to exclude from them the issues that did not pass the test according to the criteria of evidence-based medicine.

DECLARATIONS:

Disclosure Statement

The authors have no potential conflicts of interest to disclosure, including specific financial interests, relationships, and/or affiliations relevant to the subject matter or materials included.

Statement of Ethics

The authors have no ethical conflicts to disclosure.

Data Transparency

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