
PATIENTS AND THEIR ACCESS TO ETHICS COMMITTEES IN THE HEALTHCARE ESTABLISHMENTS IN THE REPUBLIC OF BULGARIA

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Abstract: Background: In health care the role of morality is increasingly being imposed, and ethically responsible behavior is seen as a prerequisite for preventing and counteracting many moral risks in society. Ethical codes are mechanisms for controlling moral hazard and responsibility, through which they represent the values and principles of different communities and groups, and create ethics committees. Ethics committees which are set up in healthcare establishments have the purpose of assisting doctors and other medical and non-medical staff in the hospital, the patients and their families and friends to resolve the ethical and legal matters that they face on a daily basis. They serve as a point of reference in resolving disputes in the area of medical ethics. Improving the work of ethics committees in healthcare establishments in the country is only possible by raising awareness of their functions and the benefits of their existence.

The aim of the study is to raise the awareness of patients about the ethics committees in the medical establishments in the country to create an objective prerequisite for their more efficient functioning.

Materials and Methods: Didactic, sociological and mathematical-statistical methods were used in the study.

Results: In the period 01.07.2018 to 01.09.2018. a survey was conducted involving 252 patients, of whom only 10.3% said they were aware of the existence of ethics committees in the medical establishments. 61.9% of respondents said they were not aware of when the ethics committees could refer, while 65.9% said they were not aware of the existence of such committees in the hospital where they were registered and treated as patients. Results show that patient awareness is at a very low level, and opportunities should be sought to reverse this negative trend.

Conclusions: The systematic training of patients in the country on ethics committees, their functions and the usefulness of their functioning would facilitate communication between the staff of healthcare establishments, patients and their relatives and would reduce their indiscriminate referral, especially in cases where there is no factual or legal complexity. It is necessary to create national information stamps covering the territory of the whole country and to improve the patients' awareness of the ethics committees in the medical care national level.

Keywords: Patients, ethics committees, healthcare establishments

1. INTRODUCTION

In health care the role of morality is increasingly being imposed, and ethically responsible behavior is seen as a prerequisite for preventing and counteracting many moral risks in society [1,2]. Ethical codes are mechanisms for controlling moral hazard and responsibility, through which they represent the values and principles of different communities and groups, and create ethics committees [3]. The medical establishments in the Republic of Bulgaria are an essential component of the national healthcare system [4]. Ethics committees based on the principles of medical ethics and medical law are founded at such healthcare establishments so as to perform the following fundamental functions: drafting statements on incoming complaints by patients or their representatives, as well as initiating inquiry procedures in the case of unethical relationships arising between hospital personnel members and patients, or between the former and the under- and post graduate students at the relevant healthcare institution [5]. They are an independent expert and consultative body providing assessments and opinions on the ethical aspects of the provided medical services, as well as the ethical aspects of research activities in the healthcare establishment [6]. Ethics committees constitute the linking unit between society's values and the healthcare establishment in which certain patients are treated and in which case ethical dilemmas arise [7]. The basic principles on which the ethics committees are established and operate include those of independence, competence, transparency and dialogue [8]. Ethics committees which are set up in healthcare establishments have the purpose of assisting doctors and other medical and non-medical staff in the hospital, the patients and their families and friends to resolve the ethical and legal matters that they face on a daily basis [9]. They serve as a point of reference in resolving disputes in the area of medical ethics [10]. Improving the work of ethics committees in healthcare establishments in the country is only possible by raising awareness of their functions and the benefits of their existence.

2. MATERIALS AND METHODS

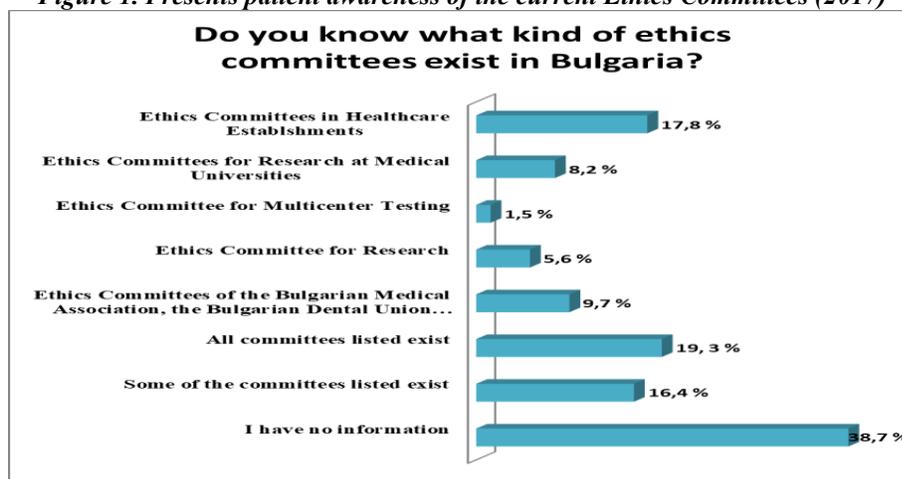
A survey was conducted to check patients' awareness of the existence of ethics committees in healthcare establishments in the country in 2017. It was attended by 269 patients treated at the following hospitals in the

country - Hospital Doverie - Sofia, First Hospital - Sofia EAD and Hospital Atanas Dabovski AD - Kardzhali. The survey was conducted in the period 05.01.2017 - 05.02.2017. The choice of medical establishments was random, two medical establishments for hospital care in Sofia, the capital of the Republic of Bulgaria (one private medical establishment and one state) and one in the town of Kardzhali (state medical institution). The selection of the patients surveyed was also random, which makes it possible to claim that the results were representative.

3. RESULTS AND DISCUSSION

With regard to patient awareness of the current Ethics Committees on the territory of the country, **Figure 1** presents the distribution of responses among all 269 patients surveyed in the three healthcare establishments.

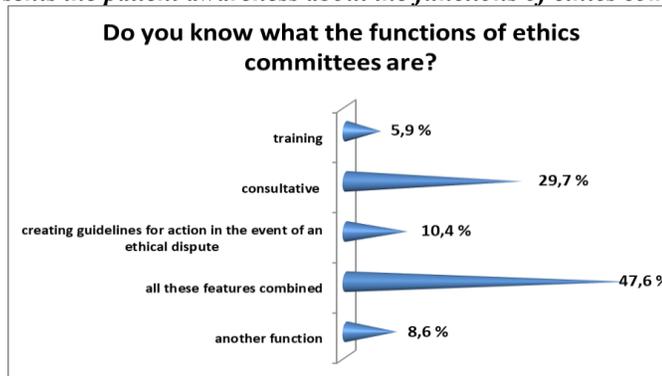
Figure 1. Presents patient awareness of the current Ethics Committees (2017)



Only 17.8% of the patients surveyed in 2017 were aware that ethics committees exist and are operating in healthcare establishments.

With regard to the awareness of the specific functions of the current ethical committees in the country, **Figure 2** presents patient awareness.

Figure 2. Presents the patient awareness about the functions of ethics committees (2017)



Only 5.9% of all patients surveyed consider the ethics committee function to be training only, and 29.7% said the ethics committee advisory function.

A total of 10.4% believe that ethics committees create guidelines and guidelines for action in the event of an ethical dispute, and the overwhelming majority of 47.6% of patients surveyed believe that ethics committees fulfill all of the functions listed as a possible answer, namely: a training function, advisory function, competent to create guidance and guidance for action in the event of a dispute.

Only 8.6% of respondents believe that ethics committees have other functions that are not reflected as a possible answer to the question asked.

Table 1 presents patients' views on the ability of ethics committees to protect and respect their rights.

Table 1 Presents patients' views on the ability of ethics committees to protect and respect their rights (2017)

Possible answer	Absolute frequency	Relative frequency	Percentage of valid answers	Cumulative percentage
Yes, completely	83	30,9	30,9	30,9
Yes - partially	100	37,2	37,2	68,0
No	17	6,3	6,3	74,3
I can not decide	69	25,7	25,7	100,0
Total	269	100,0	100,0	

In a total of 269 patients surveyed, 30.9% believe that ethics committees fully lead to the protection and respect of patients' rights, and 37.2% believe that ethics committees partially lead to the protection and respect of patients' rights.

Only 6.3% of all patients believe that ethics committees do not lead to the protection and respect of patients' rights, with 25.7% of patients declaring that they cannot judge whether ethics committees lead to the protection and respect of patients' rights.

The level of patient awareness of cases where an ethics committee may be referred, in accordance with the applicable rules of national law, is reflected in the **Figure 3**.

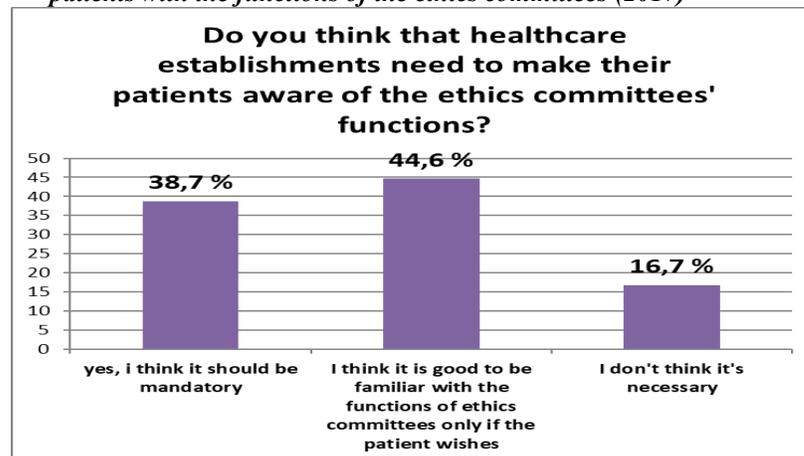
Figure 3. Presents patients' awareness of their ability to approach ethics committees (2017)



When asked "Do you know when you can refer to ethics committees?", Out of a total of 269 surveyed patients, 101 (37.5%) said they knew when they could approach ethics committees, while more than ½ of those surveyed (or 168 patients), which is 62.5% said they did not know when ethics committees could be brought.

Figure 4 presents the patients' opinion on the need for the medical establishments to familiarize patients with the functions of the ethics committees.

Figure 4. Presents the patients' opinion on the need for the medical establishments to familiarize patients with the functions of the ethics committees (2017)



In a study of the need for healthcare establishments to familiarize their patients with the ethics committee functions created in them, a total of 38.7% of all 269 patients surveyed said that healthcare establishments must make their patients aware of the ethics committee functions in them. As many as 44.6% of people said that healthcare establishments should familiarize their patients with the functions of the ethics committees in them only if the patient wishes. Only 16.7% believe that healthcare establishments do not need to familiarize their patients with the ethics committee's functions.

In response to the results obtained, the low awareness among patients and their strong position on the need to be aware of the functions of ethics committees in healthcare facilities, in 2018 an information guide was developed and printed, based on the existing national and European regulations concerning the existence and the functioning of the various types of ethics committees intended to inform patients in the country. The guidance provided background information on ethics committees, their functions, types of ethics committees and their role in the process of initiating and conducting clinical trials.

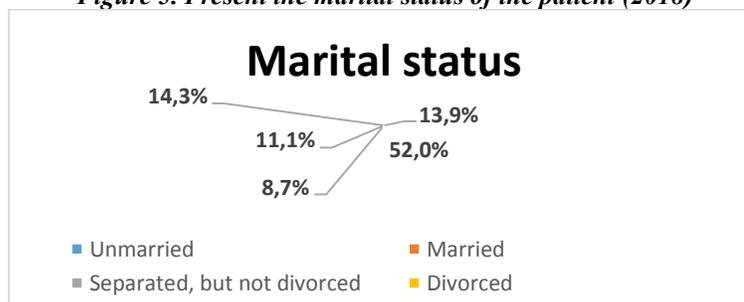
In the same three establishments where patient surveys were conducted in 2017, training seminars aimed at patients were organized and conducted in June 2018. The training seminars were held on the territory of the Hospital "Doverie" - Sofia, First Hospital - Sofia EAD and the Hospital "Dr. Atanas Daffovski" AD - Kardzhali. The choice of medical establishments was not accidental. Each of the seminars included a brief presentation on the existing ethics committees in the field of healthcare operating on the territory of the country and a discussion between the presenting team and the patients at each specific hospital. The presentation included general information on ethics committees in healthcare, the legal framework governing their operation, the types of ethics committees, the functions of ethics committees, the purpose and usefulness of their work. The low awareness among patients involved in the discussion of the usefulness and need for the existence and functioning of ethics committees did not allow the discussion to be expanded and deepened, as there was a lack of patient activity. During the presentations, the present patients were given information guides already prepared and printed.

In order to check the effect and usefulness of the prepared information guides and the presented presentations in the period from 01.07.2018 to 01.09.2018, a questionnaire was again conducted, in which 252 patients were interviewed, of which 38.5% were men and 61.5 % women. All the surveyed patients were registered and treated as patients in the following hospitals, 29.4% of the patients were interviewed in First MBAL-Sofia EAD, 34.1% of the respondents were interviewed in MBAL DOVERIE in Sofia, and 36.5% of all 252 interviewed patients were interviewed in the hospital Dr. Atanas Dafovski AD, Kardjali.

The mean arithmetic age of the patients surveyed was 54 (with a standard deviation of 16), with patients from different age groups taking part in the study.

Patients were asked what their marital status was, **Figure 5**.

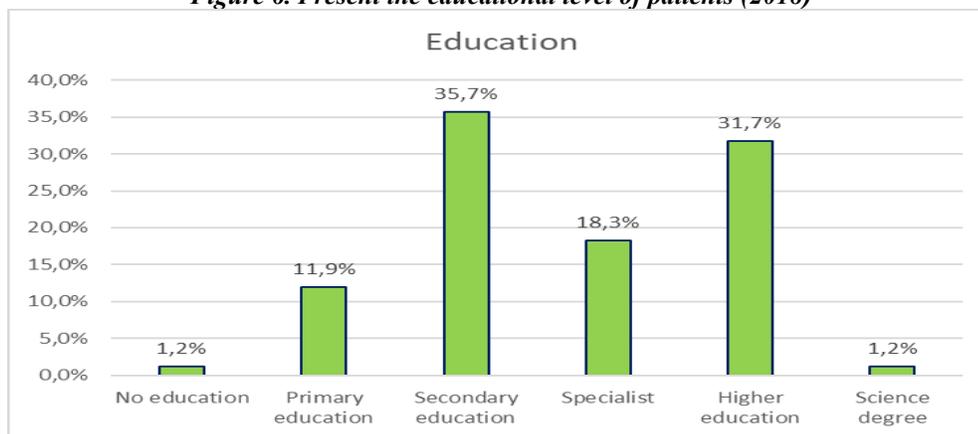
Figure 5. Present the marital status of the patient (2018)



13.9% of the patients surveyed indicated that they were unmarried, 52% said they were married, 8.7% of the recipients said they were separated, but not divorced, 11.1% said they were divorced and 14.3% said they were widowed.

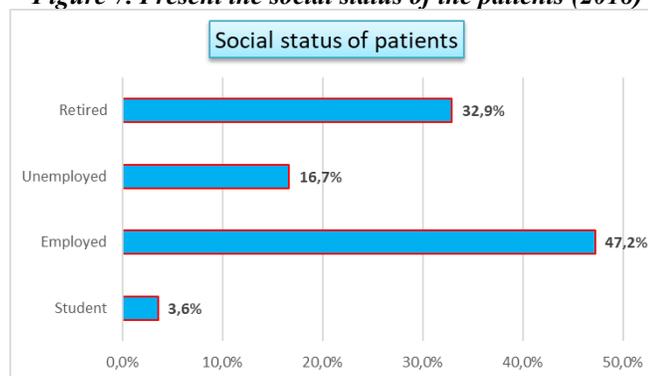
Education of the surveyed patients: no education-1.2%, primary education-11.9%, secondary education -35.7%, specialist-18.3%, higher education -31.7%, science degree -1.2%, **Figure 6**.

Figure 6. Present the educational level of patients (2018)



Patients were asked what their social status was (Figure 7).

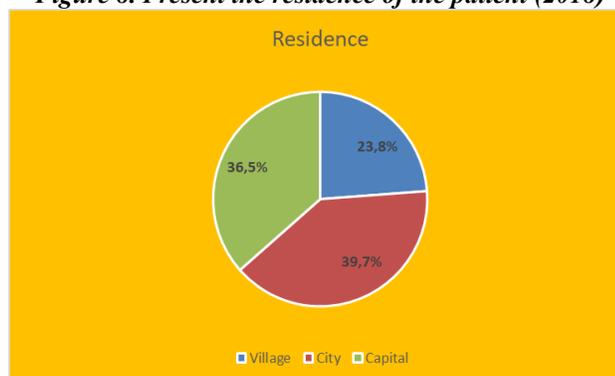
Figure 7. Present the social status of the patients (2018)



The social status of the surveyed patients: 3, 6% of them indicate that they are students, 47,2% answered that they are employed, 16,7 % indicate that are unemployed and 32,9 % said that they are retired.

The residence of the patients (Figure 8) was also examined.

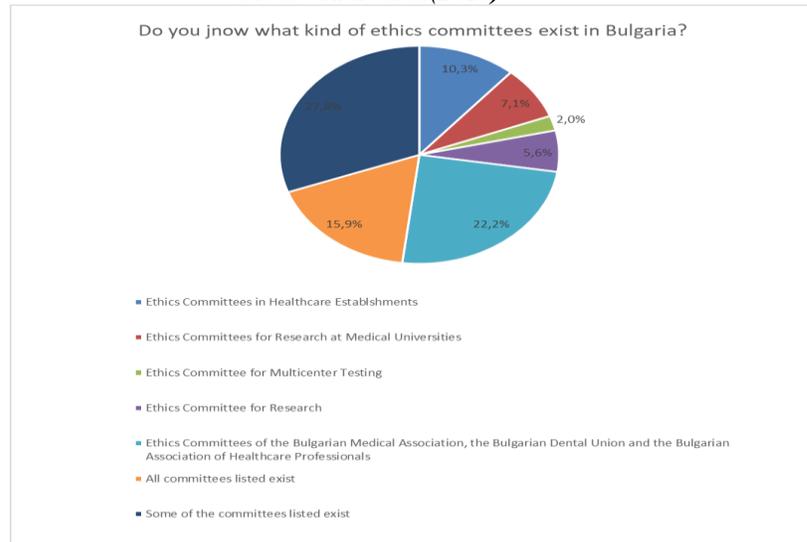
Figure 8. Present the residence of the patient (2018)



36.5% of the surveyed patients indicated that they live in the capital of the country, 39.7% indicated that they lived in a city and 23.8% said they lived in villages.

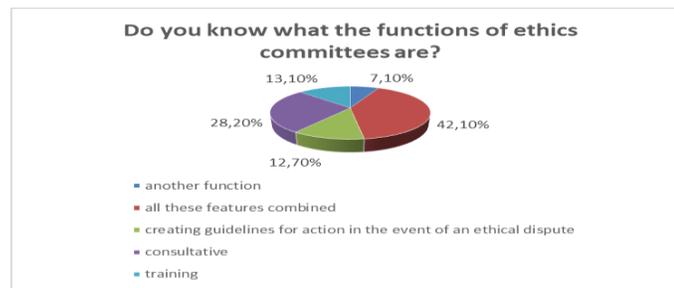
Patients were asked “Do you know what types of ethics committees exist in Bulgaria?” (Figure 9), with the following answers: Ethics committees in healthcare establishments - 10.3%; ethics committees for research at Medical Universities-7.1; ethics committees for multi-center trials-2.0%; ethics committees for scientific research - 5.6%; ethics committees of the Bulgarian Medical Association, the Bulgarian Dental Union and the Bulgarian Association of Healthcare Professionals -22.2%; all committees listed exist-15.9%; some of the committees listed exist-27.8%.

Figure 9. Present the awareness of the patients about the types of existing ethics committees(2018)



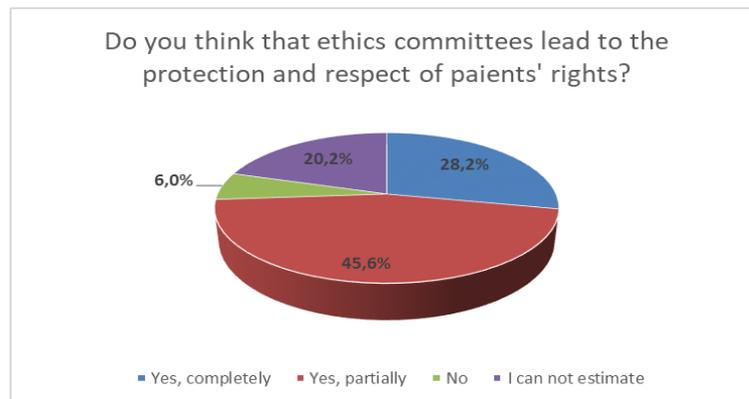
When asked “Do you know what the functions of the ethics committees are?” The answers given are the following: training-13.1%; consultative-28.2%; creating manuals and guidelines-12.7%; all listed-42.1%; another-7.1% (Figure 10).

Figure 10. Present the awareness of the patients about the function of ethics committees (2018)



Patients answered the question "Do you think that ethics committees lead to the protection and respect of patients' rights?" (Figure 11).

Figure 11. Present patients' views on the usefulness of ethics committees to patients (2018)



More than seventy percent of all patients surveyed believe that ethics committees support patients and are helpful to them in one way or another.

To the question "In your opinion, is it helpful to compile and distribute information guides/brochures on existing ethics committees?" patients responded as follows: yes, it enriches the knowledge of medical professionals in the country and supports the work of ethics committees - 44%; yes, although the information should be provided to the

healthcare professionals during their training process - 18.7%; yes, although I am not sure about the actual effect of their distribution - 15.5%; no, I do not think it is necessary-10.3%; I can not estimate-11.9% (**Table 2**).

Table 2. Present patients' view on the distribution of information guides/brochures on ethics committees

		Number of patients responded	Percentages of answers provided
In your opinion, is it helpful to compile and distribute information guides/brochures on existing ethics committees?	Yes, it enriches the knowledge of medical professionals in the country and support the work of ethics committees	111	44,0%
	Yes, although the information should be provided to the healthcare professionals during their training process	47	18,7%
	Yes, although I'm not sure about the actual effect of their distribution	39	15,5%
	No, I don't think it's necessary	26	10,3%
	I can not estimate	30	11,9%

Analyzing the results presented in Table 2, we can see the categorical position of the patients. Nearly 80 percent of respondents believe it is necessary to compile and disseminate information guides / brochures on existing ethics committees. There is a clear awareness of the problem of lack of awareness and the need for change. Raising awareness is the only and sure way to improve the functioning of ethics committees in the country.

In order to take into account the impact of the awareness campaigns and the printed information guides, we will analyze and compare the results of the 2017 ethics committee survey among 269 patients treated at Dovere Hospital, Sofia. Sofia EAD and Dr Atanas Dafovski Hospital - Kardzhali and a survey conducted in 2018 of 252 patients again treated at the same medical establishments listed above.

Table 3 presents patients' awareness in 2017 and their awareness after the training seminars and information brochures issued in 2018 on the types of ethics committees that exist in Bulgaria.

Do you know what kind of ethics committees exist in Bulgaria?	year			
	2017		2018	
	n	%	n	%
Ethics Committees in Healthcare Establishments	48	17,8%	26	10,3%
Ethics Committees for Research at Medical Universities	22	8,2%	18	7,1%
Ethics Committee for Multicenter Testing	3	1,1%	5	2,0%
Ethics Committee for Scientific Research	15	5,6%	14	5,6%
Ethics Committees of the Bulgarian Medical Association, the Bulgarian Dental Union and the Bulgarian Association of Healthcare Professionals	26	9,7%	33	13,1%
All committees listed exist	52	19,3%	56	22,2%
Some of the committees listed exist	44	16,4%	40	15,9%
I have no information	104	38,7%	70	27,8%

Table 3. Present the awareness of the patients about the existing ethics committees in Bulgaria (2017-2018)

Table 3 shows that in 2017, 17.84% of the patients surveyed answered that they were aware of the existence of Ethics Committees in healthcare establishments, and in 2018, only 10.32% said they were aware that in there are ethics committees. However, there is a positive trend among other answers given: the Ethics Committee for Multicenter Trials (1.12% in 2017 and 1.98% in 2018), the Ethics Committees at the BDA, BSA and BAPG (9.67% in 2017 and 13.10% in 2018). Despite the awareness meetings and campaigns conducted and the information manuals distributed at the three healthcare establishments in the country, patient awareness of the question asked has improved slightly and this has not produced satisfactory results. Obviously, such information campaigns have a positive impact, but the process is too slow and requires systematic delivery of information.

Table 4 presents and compares the answers to the question "Do you know when ethics committees can be referred to medical practice?" Given by the surveyed patients in the 2017 and 2018 survey. In 2017, 101 respondents or 37.50%

of patients responded that they were aware of when they could approach ethics committees, and in 2018, 90 respondents or 35.70% responded that they were informed about ethical referral options commissions. This issue has seen a slight decline in patient awareness, but this negative trend is negligible.

Table 4. Present and compare the answers of patients on their awareness of when ethics committees can be referred

Do you know when ethics committees in medical practice can be referred?	year			
	2017		2018	
	n	%	n	%
Yes	101	37,5%	90	35,7%
No	168	62,5%	156	61,9%
When...	0	0,0%	6	2,4%

Table 5 presents the views of patients reported in 2017 and 2018 on the need for healthcare facilities to familiarize their patients with the ethics committee's functions.

Table 5. Present and compare the answers of patients on the need for healthcare establishments to familiarize their patients with the functions of the ethics committees

Do you think that healthcare establishments need to make their patients aware of the ethics committees' functions?	year			
	2017		2018	
	n	%	n	%
Mandatory	104	38,7%	91	36,1%
At the request of the patients	120	44,6%	92	36,5%
I don't think it's necessary	45	16,7%	69	27,4%

In 2017, 38.66% of patients were of the opinion that health care institutions should be obliged to introduce their patients to the functions of the ethics committees in them, while in 2018, 36.11% of the patients surveyed indicated this answer. According to 44.61% of the surveyed patients the information from the medical establishments about the ethical committees in them should be provided at the expressed desire of the patient, while in 2018 only 36.51% of the respondents answered that an initial expressed wish from the side is needed the patient. In 2017, only 16.73% of respondents said that healthcare institutions do not need to provide information to their patients about the ethics committees in them, while in 2018, as many as 27.38% of those surveyed or 69 patients were is of the opinion that healthcare institutions do not need to provide information to their patients on the ethics committees' functions.

The lack of interest and willingness to raise patient awareness during the analyzed years in the country is explained by the lack of knowledge about the usefulness of the functioning of ethics committees in medical establishments. It is necessary to develop and implement such regular information campaigns to be implemented in every hospital in the country, as well as to enact a more detailed regulation on ethics committees.

It is necessary to form a will for change not only at the managerial level in the medical establishments in the country, but also at the level of the executive and legislative power in the state. Possible legislative changes and unified rules for the functioning of ethics committees in hospitals in the country would facilitate their work and create continuity between the members of the ethics committees themselves, as well as between medical professionals and patients.

Public health education needs to be encouraged and more innovative projects targeted at both healthcare professionals and patients are created and developed.

4. CONCLUSION

The systematic training of patients in the country on ethics committees, their functions and the usefulness of their functioning would facilitate communication between the staff of healthcare establishments, patients and their relatives and would reduce their indiscriminate referral, especially in cases where there is no factual or legal complexity It is necessary to create national information stamps covering the territory of the whole country and to improve the patients' awareness of the ethics committees in the medical care national level.

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